Attachment C

Comments Received In Opposition

April 17, 2006

Jan E. Perez
Board of Pharmacy
1625 North Market Boulevard
Suite N. 219
Sacramento, CA 95834
Via facsimile (916) 574-8618

Re: Proposed Regulation Division 17, Title 16, sections 1793.7(b) and 1793.8 of the California Code of Regulations "Pharmacy Technicians Checking Pharmacy Technicians"

The United Food and Commercial Workers Union, Western States Council, is opposed to the regulations proposed by the Board of Pharmacy (Board) which would permit general acute care hospitals to employ specially trained pharmacy technicians in place of pharmacists to check the work of other pharmacy technicians.

Authority to Promulgate Regulations

The Board does not have the authority to promulgate the proposed regulations. While the Board does have authority to promulgate regulations relating to the practice of pharmacy pursuant to Business and Professions Code section 4005, the Board is overreaching in promulgating these particular regulations.

B & P Code section 4005 begins with the following: "[t]he board may adopt rules and regulations, not inconsistent with the laws of this state, as may be necessary for the protection of the public." The proposed regulations are inconsistent with existing state law and, rather than providing for additional consumer protection will likely increase the risk of harm borne by the public.

Existing law specifies the duties which may only be undertaken by licensed pharmacists (B & P Code sections 4050 et seq.) and those which may be undertaken by licensed pharmacy technicians (B & P Code section 4115), under the direct supervision of a pharmacist.

Specifically, B& P Code section 4115(a) limits the duties which may be undertaken by a pharmacy technician to "...nondiscretionary tasks, only while assisting, and while under the direct supervision and control of a pharmacist." Additionally, B & P Code section 4115(c) specifies that pharmacist technicians are not authorized "to perform any act requiring the exercise of professional judgment by a pharmacist." Finally, B & P Code

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section 4115(h) specifies that pharmacists "shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist."

Existing regulations support the limitations on pharmacy technicians imposed by statutory law. Specifically, California Code of Regulations section 1793.7 states that "Any function preformed by a pharmacy technician in connection with the dispensing of a prescription, including repackaging from bulk and storage of pharmaceuticals, must be verified and documented in writing by a pharmacist."

Accordingly, both existing statutory and regulatory are clear in the limitations imposed on what pharmacy technicians may and may not do, and are clear in the supervisory role which must be played by pharmacists. It would be contradictory to existing law to allow pharmacy technicians to check the work of other pharmacy technicians in lieu of that oversight being undertaken by pharmacists. Further, it would be contradictory to the provision of existing statutory law which limits the authority of the Board to promulgate regulations

Regulatory History

This is not the first time that regulations regarding the subject matter of those currently proposed have been proposed by the Board.

In 1997, UCSF School of Pharmacy, in conjunction with Cedars-Sinai Medical Center and Long Beach Memorial Medical Center petitioned the Board to grant a waiver of the California Code of Regulations requiring licensed pharmacists to check unit dose cassettes filled by pharmacy technicians in the inpatient hospital facility setting

In May 1998, the Board granted the waiver and an experimental program was implemented to determine the accuracy rate of pharmacy technicians checking the work of other pharmacy technicians as opposed to pharmacists checking the work of pharmacy technicians.

The study looked at 39 pharmacy technicians checking 161,740 doses, and 29 pharmacists who checked 35,829 doses. The 39 pharmacy technicians had a 99.8% accuracy rate as opposed to a 99.5% accuracy rate.

It is important to note three things:

First, it is not clear if the results of the study upon which this regulatory proposal relies are weighted to reflect the substantial difference in the number of pharmacist participants and dose checks as opposed to the number of pharmacy technician participants and dose checks. If the study results were not weighted to reflect those differentials then it is impossible to know what the actual accuracy rate differential is.

Second, the study upon which this regulatory proposal relies looked at only 68 individuals and only 197,569 doses. It is not sound public policy, particularly where a dramatic impact on patient care is a real possibility, to rely on such a small study.

Third, the differential in accuracy rate was only .3% -- with both groups having an above 99% accuracy rating. Clearly, the study fails to show a marked improvement of the pharmacy technicians over the pharmacists. Further, the study fails to show that improvement in this arena is imperative, as both groups had an above 99% accuracy rating.

At the January 2001 meeting of the Board, the study participants requested and the Board granted, an extension of the waiver until December 2002.

At the October 15 &16, 2001 meeting of the Board, there was a lengthy discussion of adopting a similar regulation. This discussion included comments which referenced former Deputy Attorney General William Marcus' opinion that the Board does not have the authority to promulgate a regulation of this nature (October 15 & 16, 2001, minutes, page 19) Further, according to the October 24 & 25, 2002 Board meeting minutes, "the Board decided that the proposed changes would require legislation" (minutes, page 5).

It is highly suspect that the Board would determine at a public hearing in 2002 that it did not have the authority to promulgate such regulations, and then propose the same regulations a mere four years later.

Legislative History

In 2003, SB 393 by Senator Aanestad was introduced but failed passage in the Legislature. That bill, would have authorized general acute care hospitals to implement and operate a program using specially trained pharmacy technicians to check the work of other pharmacy technicians, contained language very similar to the proposed regulations.

In 2005, SB 592, also by Senator Aanestad, containing the same language, also failed passage in the Legislature.

Both bills were supported by the Board of Pharmacy, which, presumably believed that a statutory change was necessary in order to permit technicians to check the work of other technicians without the intervention of a pharmacist.

If one reviews both the regulatory and Legislative history of this proposal it becomes clear that proponents of this proposal have made failed attempts to make the same change via both the legislative and regulatory process. It also becomes evident that there are valid arguments which have precluded passage of this proposal via both the Legislative and regulatory setting.

Potential Impact on Patient Care

B & P Code section 4001.1 states "[p]rotection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory and

disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount."

The proposed regulation does not comport with the above statutory citation. The proposed regulation will not promote protection of the public, and, to the contrary may very well result in increased dispensing error rates and associated detrimental impact to patients in the acute care setting.

Patients in the acute care setting are generally those in greatest need of a heightened level of care. Additionally, patients in the acute care setting are often prescribed multiple medications, which if taken improperly or in the wrong combination, could prove fatal. Accordingly, it does not stand to reason that pharmacy technicians rather than pharmacists (who have substantially greater educational, training and licensing requirements than do pharmacy technicians) should be checking the work of other pharmacy technicians in the acute facility setting.

"Additional Training" Requirement

While the proposed regulation specifies that pharmacy technicians authorized to check the work of other pharmacy technicians must receive "specialized and advanced" training, there is no specificity as to the qualifying requirements for such additional training and in fact, the nature of the training is left up to the individual facilities. Accordingly, a facility could determine that the "specialized and advanced" training consists of an hour long video seminar on pharmaceuticals, and such training would be in complete compliance with the proposed regulation. Pharmacists, unlike pharmacy technicians, are subject to stringent educational, training and licensing requirements. To task pharmacy technicians with the important duty of verifying the accuracy of medication doses in the acute care setting without mandating appropriate and adequate training could produce dire consequences for the patients in these facilities.

De-Skilling of the Pharmacist Profession

Where the workload of professionals is reduced, concern always arises that alternative assignments will not materialize. While the proposed regulation specifies that where pharmacy technicians are used to check the work of other pharmacy technicians, pharmacists shall be deployed to the inpatient care setting to provide clinical services, we are concerned that the pharmacists hours may be reduced or that acute care facilities will begin to see pharmacists and pharmacy technicians as interchangeable professionals. We see this proposed regulation as a step towards deskilling the pharmacist profession, and as an inappropriate response to the pharmacist shortage. As mentioned above, pharmacists have rigid educational, training and licensure requirements, which are not shared by pharmacy technicians. It is imperative that pharmacists receive the training and have the professional oversight they do because of the importance of their work to the health and safety of consumers. Pharmacy technicians can not do the job of pharmacists, because they are not trained to do so. To allow pharmacy technicians to check the work of other

pharmacy technicians is to imbue pharmacy technicians with decision making authority which is not appropriate for their level of education and training.

Liability Concerns

The proposed regulations specify that "the overall operation of the program shall be the responsibility of the pharmacist-in-charge" (proposed 1793.8(c)(1)) and that "the program shall be under the direct supervision of the pharmacist and the parameters for the direct supervision shall be specified in the facilities policies and procedures" (proposed 1793.8(c)(2). Accordingly, while the proposed regulation removes the duty of checking the work of pharmacy technicians from the purview of pharmacists in the acute care setting, it does not remove the liability of those pharmacists to ensure that the work is done accurately. We are concerned that the transition of duties, will invariably result in acute care facilities reducing the number of pharmacists they retain, while increasing the number of pharmacy technicians the work of whom the pharmacists will ultimately be responsible.

Conclusion

In conclusion, the Board should not promulgate these regulations as they are neither consistent with existing law nor are they within the scope of the authority of the Board. Additionally, these regulations could prove harmful to those patients who are in greatest need of a heightened level of care, rather than a reduction thereto. Finally, such regulations do not reduce the level of liability borne by the impacted pharmacists, while the regulations do reduce the ability of the impacted pharmacists to exert control over the tasks which could result in dispensing error.

For these reasons, on behalf of the United Food and Commercial Workers Union, Western States Council, we respectfully urge the Board to reject the proposed regulations.

Sincerely,

Barry Broad

CALIFORNIA NURSES ASSOCIATION
A Voice for Nurses – A Vision for Healthcare
www.calnurse.org

April 17, 2006

Jan E. Perez
California Board of Pharmacy
1625 North Market Blvd. Suite N 219
Sacramento, California 95834

Re: Proposed Regulations "Tech-check-tech"

Dear Ms. Perez:

Thank you for the opportunity to submit comments to the proposed regulations that would add a new *Section 1793.8 Technicians In Hospitals with Clinical Pharmacy Program* (Tech-check-tech) to Title 16 of the California Code of Regulations.

Government Code Section 11349.1 requires the Office of Administrative Law to review all proposed regulations for compliance with the following standards: necessity, authority, clarity, consistency, reference and duplication. The proposed regulations at issue fail to meet the requirements of authority, reference, necessity, clarity and consistency.

Authority
Government Code Section 11349(b) states: "'Authority' means the provision of law which permits or obligates the agency to adopt, amend, or repeal a regulation."

Reference
Government Code Section 11349(e) states: "'Reference' means the statute, court decision, or other provision of law which the agency implements, interprets, or makes specific by adopting, amending, or repealing a regulation." California Code of Regulations, Title 1, Section 14, states: "... [A]n agency's interpretation of its regulatory power, as indicated by the proposed citations to 'authority' or 'reference' ... shall be conclusive unless ... the agency's interpretation alters, amends or enlarges the scope of the power conferred upon it ..."

The regulation proposed by the California Board of Pharmacy expands the practice of Pharmacy Technicians (PTs) beyond that which is authorized for PTs in current statute. Business and Professions Code (B&P) *Section 4038 Pharmacy Technician* states:

"Pharmacy Technician" means an individual who **assists a pharmacist** in a pharmacy in the performance of his or her pharmacy related duties, as specified in Section 4115." [Emphasis added]

B&P Code *Section 4115 Pharmacy Technician; nondiscretionary tasks; direct supervision of pharmacist; registration; ratios* states, in relevant part:

4115. (a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, **only while assisting, and while under the direct supervision and control of a pharmacist.** [Emphasis added]

These "Tech-check-tech" regulations create a new category of "super-PT" who will engage not in the performance of non-discretionary tasks but rather in the performance of tasks which the Board admits in proposed Section 1793.6(c)(3) necessitates "specialized and advanced training." A role currently performed by pharmacists.

The Pharmacy Technician who would be working under the newly proposed "super-PT" role is not "assisting a **pharmacist**" and is not under the direct supervision of a pharmacist but rather under the direct supervision and control of the super-PT. "Direct supervision and control", as defined in statue to mean " that a **pharmacist** is on the premises at all times and is **fully aware** of all **activities** performed by either a pharmacy technician or intern pharmacist. The statute does not allow pharmacist to delegate that authority to a PT to directly supervise and control the work of another PT.

Non-discretionary tasks as used in Business and Profession Code 4115 is defined in CCR Title 16 Section 1793.2

"Non-discretionary tasks" as used in Business and Professions Code section 4115, include:
(a) removing the drug or drugs from stock;
(b) counting, pouring, or mixing pharmaceuticals;
(c) placing the product into a container;
(d) affixing the label or labels to the container
(e) Packaging and re-packaging.

The new category of PT will be performing a role which CCR Section 1793.1(f) and (g) defines the exclusive scope of practice of a pharmacist and which requires training beyond that required for licensure/certification as a pharmacy technician. CCR Section 1793.1 states, in relevant part:

§ 1793.1 Duties of a Pharmacist.
Only a pharmacist, or an intern pharmacist acting under the supervision of a pharmacist may:

(f) Supervise the packaging of drugs and **check the packaging procedure and product upon completion.**
(g) Perform **all** functions which require professional judgment. [Emphasis added]

In 1992, the Board adopted a requirement that **"[a]ny** function performed by a pharmacy technician in connection with the dispensing of a prescription, including pre-packaging from bulk and storage of pharmaceuticals, **must be verified** and documented in writing **by a pharmacist...**" [Emphasis added] (Register 92, No. 33). The Board appears now to assert that the same "authority" and "reference" statutes that led to regulatory clarification of this exclusive scope of practice for pharmacists now authorizes the board, without statutory change, to assign the pharmacists' practice to a pharmacy technician.

Furthermore, even if it could be argued that "Tech check tech" in the pharmacy using super-PTs to check PTs was a "non-discretionary" function, which it is not, the proposed language of 1793.8 in which super-PTs "check the work of other pharmacy technicians in connection with **the filling of floor and ward stock"** is an attempt to sneak in the extremely dangerous and the clearly non-discretionary task of placing pharmaceuticals into ward stock that is used by registered nurses and physicians during emergencies. The use of ward stock medications is a highly risk prone process in which the **wrong** strength of a floor stock medication could result in a critical error if the registered nurse or physician is in a hurry and does not pick up the technician's error. Ward stock is essential when the turn around time from the pharmacy is inadequate to need the immediate needs of patients on the care unit. However, "verbal orders" are often given to registered nurses under emergent conditions for use of medications that are a part of floor stock. The use of floor stock, although sometimes necessary, automatically eliminates one safety check by a licensed pharmacist who prepares and sends medication for a specific patient. Floor and ward stock also includes controlled substances such as narcotics. Is the Board turning over the stocking of controlled substances to pharmacy technicians? The California Cedars-Sinai project attached as materials relied upon for the proposed regulation did **not include "tech check tech" of unit or ward stock medication** in the hospital pilot project. CNA pointed this out in a 2005 legislative hearing and the bill failed to make it out of the Assembly policy committee.

Senator Aanestad authored SB 393 in 2003 [Attachment 1] and SB 592 in 2005 [Attachment 2], legislation that mirrors "tech check tech" regulatory language proposed by the Board. In both 2003 and 2005, the legislature rejected the changes. The 2003 version didn't make it out of the first policy committee and the 2005 version died in the Assembly despite prominently featured support by the California Board of Pharmacy. [Attachment 3].

It is inconceivable that legislation that was supported by the Board of Pharmacy in 2005 and was defeated in the legislature could now be adopted as regulations by the Board of Pharmacy. The authority delegated to the Board of Pharmacy by the legislature should not contravene the will of the legislature.

Recent Sacramento Superior Court decisions won by the California Nurse Association against two administrative agencies that usurped legislative authority, the California Board of Vocational Nurses and Psychiatric Technicians (BVNPT) [Attachment 4] with regulations that went through the full APA process and the California Department of Health Services (DHS) [Attachment 5] that utilized the emergency rule making process, CNA submits as evidence both cases in which administrative agencies acting not in the interest of the healthcare consumers but in the interest of the healthcare industry were rebuked by the court. CNA requests that the California Board of Pharmacy respond to all points made in these cases and explain why the Board of Pharmacy should not be held to the same standards as the BVNPT and the DHS.

Necessity
Government Code Section 11349(a) states: "'Necessity' means the record of the rulemaking proceeding demonstrates by substantial evidence the need for a regulation to effectuate the purpose of the statute, court decision, or other provision of law that the regulation implements, interprets, or makes specific, taking into account the totality of the record. For purposes of this standard, evidence includes but is not limited to, facts, studies, and expert opinion."

This standard is further clarified by regulation in California Code of Regulations, Title 1, Section 10, in relevant part:

> *CCR, Title 1, Section 10 (b)*
> (b) In order to meet the "necessity' standard of Government Code section 11349.1, the record of the rulemaking proceeding shall include:
> **(1)** a description of the public problem, administrative requirement, or other condition or circumstance which each provision of the regulation is intended to address; **and**
> (2) information explaining why each provision of the adopted regulation is required to carry out the described purpose of the provision. Such information shall include, but is not limited to, facts, studies, or expert opinion. When the explanation is based upon policies, conclusions, speculation, or conjecture, the rulemaking record must include, in addition, supporting facts, studies, expert opinion or other information. An "expert" within the meaning of this section is a person who possesses special skill or knowledge by reason of study or experience **which is relevant to the regulation in question**. [Emphasis added]

Here, neither aspect of this standard has been met. First, there has been no showing whatsoever of the need for the proposed regulation – the problem,

requirement, condition or circumstance it is intended to address. Hospitals already have the authority to dispatch pharmacists to patient care unit. No regulation is necessary to implement that change. In addition, we believe that this proposal is unauthorized and is inconsistent with Business and Professions Code Section 4001.1

> *Section 4001.1 Protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.*

Protection of the public is to be the highest priority for the California State Board of Pharmacy and yet the article submitted by the Board evidences a complete lack of regard for that mission. The article submitted by the Board entitled *"Interrelationships among Mortality Rates, Drug Costs, Total Cost of Care, and Length of Stay in United States Hospitals: Summary and Recommendations for Clinical Pharmacy Services and Staffing* [1] (*Recommendations for Clinical Pharmacy Services and Staffing*) evaluated, retrospectively, the relationship between hospital mortality rate based on 1992 Health Care Financing Administration for hospital, drug costs, total costs of care and length of stay in from the 1992 American Hospital Association's Abridged Guide to the Health Care Field and the 1992 National Clinical Pharmacy Services data base.

It should be noted that this paper admits that is shows *only correlations* between pharmacy care services, the "quality" indicator patient mortality and the fiscal indicators of drug costs, total costs of care and hospital length of stay. There is no causal relationship shows in this analysis. *Recommendations for Clinical Pharmacy Services and Staffing* states:

> "The relationship between the severity of illness-adjusted death rate...and drug cost/occupied bed...is rather striking. **As drug costs increased...the death rate declined** from 91/1000 to 72/1000 admission, a 21% decline." [2] [Emphasis added]
>
> ".. mortality rates are a very good indicator of quality of care it appears that higher hospital costs predict better patient care."[3]

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[1] C.A. Bond, Pharm. D., et. al, *Interrelationships among Mortality Rates, Drug Costs, Total Cost of Care, and Length of Stay in United States Hospitals: Summary and Recommendations for Clinical Pharmacy Services and Staffing* , Pharmacotherapy 2001; 21 92): 129-141.

2 C.A. Bond, Pharm. D., et. al., Interrelationships among Mortality Rate, Drug Costs, Total Cost of Care, and Length of Stay in United States Hospital: Summary and Recommendations for Clinical Pharmacy Services and Staffing, p. 136.

3 C.A. Bond, Pharm. D., et. al, Interrelationships among Mortality Rates, Drug Costs, Total Cost of Care, and Length of Stay in United States Hospitals: Summary and Recommendations for Clinical Pharmacy Services and Staffing , Pharmacotherapy 2001; 21 92), p. 137.

> "Increased dispensing pharmacist staffing was associated with **reduced mortality rates,** but **increased drug costs**..."[4] [Emphasis added]

The authors conclude, 'If we are to effect major healthcare outcome measures **and reduce costs,** it appears that we should significantly increase clinical pharmacist staffing and **reduce** ... **dispensing pharmacist staffing.**" [5] [Emphasis added] This doesn't make sense. Increased dispensing pharmacist staffing was associated with decreased mortality and increased drug costs and increased drug costs were associated with decreased mortality. The Board recommends decreasing costs and decreasing dispensing pharmacist.

Recommendations for Clinical Pharmacy Services and Staffing also states:

> "The relationship between the **severity of illness-adjust death rate**... and **total cost of care/occupied bed is impressive. As total costs increased... the death rate declined** from 105/1000 to 68/1000 (35% decline). "[6] [Emphasis added]

> "Reasons for findings between total cost of care and mortality rates are unknown. This relationship is not unexpected, since the largest component of a hospital's cost structure is personnel, and **increased staffing levels of medical residents, registered nurses, pharmacists, medical technologists, and total hospital personnel are associated with lower mortality rates.**" [7] [Emphasis added]

The California Board of Pharmacy's mandate is to protect the **public,** not protect corporate healthcare's pocket book. More importantly, the correlation between increased dispensing pharmacist staffing, increased drug costs, and increased total cost correlate, according to the study's authors, with **decreased mortality rates.** The authors recognize that increased staffing other than on unit pharmacists contributes to patient outcomes and yet they conclude without any real evidence that the associations they saw were related solely to the use of

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3 Ibid.

4. Ibid.

5. Ibid.

6. Ibid., p. 135.

7. Ibid., p. 137

clinical pharmacists on the patient care unit. The contradictions in this article are obvious and pervasive.

Neither regulatory nor statutory change is necessary for the use of licensed pharmacist in acute care hospitals in either the "dispensing" role or in the role of the pharmacist as a part of the healthcare team on the acute care hospital patient care unit (the "clinical" pharmacist defined in this article). The California Nurses Association is not arguing that pharmacist should not be used on patient care units as part of the healthcare team. CNA believes that this added surveillance of healthcare services protects patients and places another layer of checks and balances between the dispensing pharmacists and the patient. Registered nurses must pick up both dispensing errors and prescribing errors before they harm patients. Time constraints and other diversions impact their ability to perform that protective role effectively. The presence of a pharmacist on each unit to provide professional services can significantly enhance the quality of patient care services. The Board has not demonstrated, however, that the **deskilling of pharmacy dispensing** is safe for patients.

Consistency
Government Code Section 11349(d) states: "'Consistency' means being in harmony with, and not in conflict with or contradictory to, existing statutes, court decisions, or other provisions of law."

Proposed new regulations, Section 1793.8(c) proposes "...programs that use pharmacy technician to check the work of other pharmacy technicians must include the following components...(3) The pharmacy technician who performs the checking function has received specialized and advanced training **as prescribed in the policies and procedures of the facility.**"

CCR *§ 1793.6. Training Courses Specified by the Board* states that a Pharmacy Technician course of training must be accredited by the American Society of Health-System Pharmacists, be provided by a branch of federal armed services or be 240 hours in length covering specific areas of PT and pharmacy practice. The Board's proposal to leave "specialized and advanced" training to acute care hospitals is in conflict with existing regulations.

Here, as discussed above under Authority, the proposed regulations are in direct conflict with the statute they purport to implement

Clarity
Government Code Section 11349(c) states: "'Clarity' means written or displayed so that the meaning of regulations will be easily understood by those persons directly affected by them."

The term "clinical pharmacy program" used in the proposed regulations lack clarity. The 2006 Law Book for Pharmacy contains 840 references to the term

"pharmacist", 2 references to "licensed pharmacist", 8 references to "registered pharmacist" and 5 references to "dispensing pharmacist". No definition of or reference to "clinical pharmacists" or to "clinical pharmacy program" exists in the statutes or regulations in the 2006 compilation of laws and regulations. The use of these terms is confusing.

Thank you for the opportunity to provide initial comments on these proposed regulations. CNA will attend the hearing scheduled for April 26 and will provide further comments at that time.

Sincerely,

Vicki Bermudez

Vicki Bermudez RN
Regulatory Policy Specialist
California Nurses Association

ATTACHMENT 1

AMENDED IN SENATE JULY 16, 2003

SENATE BILL **No. 393**

Introduced by Senator Aanestad

February 20, 2003

An act to add Article 7.6 (commencing with Section 4128) to Chapter 9 of Division 2 of the Business and Professions Code, relating to pharmacists.

LEGISLATIVE COUNSEL'S DIGEST

SB 393, as amended, Aanestad. Pharmacists: inpatient pharmacy technician services.

Existing law, the Pharmacy Law, authorizes the California State Board of Pharmacy to regulate, license, register, and discipline pharmacists and pharmacy technicians. Existing law authorizes a pharmacy technician working in an inpatient hospital or a correctional facility to perform nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist.

This bill would authorize a general acute care hospital to implement and operate a program using specially trained pharmacy technicians to check the work of other pharmacy technicians who have filled floor and ward stock and unit dose distribution systems for patients whose pharmacy prescriptions have been previously reviewed by a licensed pharmacist. The bill would require a hospital that operates this program to keep a list of all qualified pharmacy technicians available for board inspection and to keep all required data in the hospital for at least 3 years.

Existing law makes it a misdemeanor to knowingly violate the Pharmacy Law. Because violations of this bill would be a misdemeanor, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares that:

(a) Pharmacists have emerged as critical members of a medical team by providing services such as patient education, drug therapy monitoring, and pharmacokinetic consultations. Pharmacists often work side by side with physicians and nurses, and participate in medical rounds. Pharmacists play an integral role in ensuring a safe medication use process. Through interpretation, evaluation, and clarification of orders, pharmacists ensure the absence of drug allergies, interactions, duplications, and the optimal selection of dose, dosage form, frequency, route, and duration of therapy.

(b) There currently exists a shortage of pharmacists in the state, and this shortage has the potential to cause harm to patients because hospitals lack sufficient staffing to fully take advantage of clinical pharmacy programs that have been shown to reduce the number of medication errors in hospitals and improve patient outcomes.

(c) Studies authorized by the California State Board of Pharmacy, and conducted under the direction of the University of California, San Francisco, at major California hospitals, have established that certain nondiscretionary functions currently performed by pharmacists in the hospital setting can safely be performed by properly trained pharmacy technicians. Specifically, allowing properly trained pharmacy technicians to check certain tasks performed by other pharmacy technicians is a safe and efficient use of staff, and frees pharmacists to provide the more important and skilled clinical pharmacy services that are critical to quality patient care and the reduction of medication errors.

(d) Pharmacists are substantially over-qualified for performing these nondiscretionary inpatient checking functions, and current

rules that require pharmacists to perform these functions unnecessarily limit hospitals in their capacity to fully provide patients with clinical pharmacy services.

(e) It is the intent of the Legislature in enacting this act that pharmacists remain responsible for pharmacy operations. Nothing in these provisions should be interpreted to eliminate or minimize the role of pharmacists in directly supervising pharmacy technicians and pharmacy operations. It is the further intent of the Legislature that hospitals take advantage of the efficiencies created by these provisions by using properly trained pharmacy technicians for certain nondiscretionary checking functions and more completely utilize the training and skills of their pharmacist staff to implement and expand clinical pharmacy programs at their facilities.

SEC. 2. Article 7.6 (commencing with Section 4128) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 7.6. Inpatient Pharmacy Technician Services

4128. (a) Notwithstanding any other provision of law, a general acute care hospital, as defined in subdivision (a) of Section 1250 of the Health and Safety Code, may implement and operate a program utilizing specially trained pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for patients admitted to the hospital whose orders have previously been reviewed by a licensed pharmacist. The hospital may implement and operate this type of a program if all of the following requirements are met:

(1) The hospital conducts ~~an ongoing~~ *a special* training program ~~pursuant to criteria the board, by regulation, has adopted for training pharmacy technicians. This criteria shall include both didactic and practical elements. Prior to adopting these regulations, the board shall approve a hospital's request to implement a pharmacy technician program if it is satisfied that the hospital has an adequate training program and meets the other requirements of this section.~~ *for technicians who perform the checking function that satisfies the requirements of subdivision (b).*

(2) The hospital conducts a continuous quality improvement program that, at a minimum, audits the performance of the specially trained pharmacy technicians at least every three months for the first year, and annually thereafter. A pharmacy technician whose audited accuracy rate falls below 99.8 percent shall not be permitted to check the work of other pharmacy technicians until he or she is requalified pursuant to paragraph (1).

(3) The hospital has a current nonprovisional, nonconditional accreditation from the Joint Commission on the Accreditation of Healthcare Organizations or another nationally recognized accrediting organization.

(4) The hospital pharmacy has been inspected by the board.

(5) The hospital establishes and maintains a program utilizing pharmacists to provide clinical services as described in Section 4052.

(b) *The training program required by paragraph (1) of subdivision (a) shall include both didactic and practical elements, and shall specify requirements to be completed prior to the technician commencing participation in the checking program.*

(1) The didactic component of the training shall consist of at least four hours of education covering the following topics:

(A) Information required to be on the label of unit dose or extemporaneous packaging.

(B) Identification of expired or contaminated medications.

(C) The product characteristics that need to be checked for each drug dispensed from the pharmacy.

(D) Special packaging or handling requirements, including refrigeration for certain medications.

(E) Generic names for common name-brand medications.

(F) Recognition and identification of various dosage forms.

(G) Common medical abbreviations and symbols used in pharmacy.

(H) Basic mathematical principles used in pharmacy calculations, including conversions between and within metric, avoirdupois, and apothecary systems.

(2) The practical component of the training shall consist of at least two hours of supervised practice in which the trainee both observes proper checking procedures and performs proper checking procedures under the direct observation of the supervisor.

(c) The board may, by regulation, establish other rules for hospitals utilizing specially trained pharmacy technicians ~~pursuant to this section. The board shall adopt regulations establishing the criteria described in paragraph (1) of subdivision (a).~~ *pursuant to this section.*

~~(c)~~

(d) The board may order a hospital to cease activities authorized by this section at any time a hospital fails to satisfy the board that it is capable of continuing to meet the requirements of this section.

~~(d)~~

(e) Data and records required by this section shall be retained in each participating hospital for at least three years.

~~(e)~~

(f) Medication that has been placed in floor or ward stock or unit dose distribution systems pursuant to this section shall not be administered to a patient except by a licensed health care provider practicing within the scope of his or her license.

~~(f)~~

(g) Legal responsibility or liability for errors or omissions that occur as a result of a pharmacy technician checking another pharmacy technician's work pursuant to this section shall be limited to the holder of the pharmacy permit and the pharmacist in charge.

4128.1. (a) Every hospital utilizing pharmacy technicians to check the work of other pharmacy technicians pursuant to Section 4128 shall maintain for inspection by the board a current list of all pharmacy technicians that have been qualified to perform checking functions.

(b) A pharmacy technician is not eligible to be qualified pursuant to this article unless he or she:

(1) Is currently certified by the Pharmacy Technician ~~Certifying~~ *Certification* Board.

(2) Is currently registered with the board as a pharmacy technician pursuant to Section 4202.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty

for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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ATTACHMENT 2

AMENDED IN SENATE MARCH 29, 2005

SENATE BILL **No. 592**

Introduced by Senator Aanestad

February 18, 2005

An act to add Article 7.6 (commencing with Section 4128) to Chapter 9 of Division 2 of the Business and Professions Code, relating to pharmacy technicians.

LEGISLATIVE COUNSEL'S DIGEST

SB 592, as amended, Aanestad. Acute care hospitals: inpatient pharmacy technician services.

Existing law, the Pharmacy Law, provides for the regulation of the practice of pharmacy by the California State Board of Pharmacy, in the Department of Consumer Affairs. Existing law authorizes a registered pharmacy technician to assist in the performance of pharmacy related duties under the supervision of a licensed pharmacist. A violation of the Pharmacy Law is a crime.

This bill would authorize a general acute care hospital to implement a program utilizing specially trained pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for certain patients, if specified requirements are met. *The bill would require a hospital that operates this program to keep a list of all qualified pharmacy technicians available for board inspection and to keep all required data in the hospital for at least 3 years.*

Because a failure to meet the training *and other* requirements in this bill would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state.

Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) Pharmacists have emerged as critical members of a medical team by providing services such as patient education, drug therapy monitoring, and pharmacokinetic consultations. Pharmacists often work side by side with physicians and nurses, and participate in medical rounds. Pharmacists play an integral role in ensuring a safe medication use process. Through interpretation, evaluation, and clarification of orders, pharmacists ensure the absence of drug allergies, interactions, duplications, and the optimal selection of dose, dosage form, frequency, route, and duration of therapy.

(b) There currently exists a shortage of pharmacists in the state, and this shortage has the potential to cause harm to patients because hospitals lack sufficient staffing to fully take advantage of clinical pharmacy programs that have been shown to reduce the number of medication errors in hospitals and improve patient outcomes.

(c) Studies authorized by the California State Board of Pharmacy, and conducted under the direction of the University of California, San Francisco, at major California hospitals, have established that certain nondiscretionary functions currently performed by pharmacists in the hospital setting can safely be performed by properly trained pharmacy technicians. Specifically, allowing properly trained pharmacy technicians to check certain tasks performed by other pharmacy technicians is a safe and efficient use of staff, and frees pharmacists to provide the more important and skilled clinical pharmacy services that are critical to quality patient care and the reduction of medication errors.

(d) Pharmacists are substantially over-qualified for performing these nondiscretionary inpatient checking functions, and current rules that require pharmacists to perform these functions unnecessarily limit hospitals in their capacity to fully provide patients with clinical pharmacy services.

(e) It is the intent of the Legislature in enacting this act that pharmacists remain responsible for pharmacy operations. Nothing in these provisions should be interpreted to eliminate or minimize the role of pharmacists in directly supervising pharmacy technicians and pharmacy operations. It is the further intent of the Legislature that hospitals take advantage of the efficiencies created by these provisions by using properly trained pharmacy technicians for certain nondiscretionary checking functions and more completely utilize the training and skills of their pharmacist staff to implement and expand clinical pharmacy programs at their facilities.

~~SECTION 1.~~

SEC. 2. Article 7.6 (commencing with Section 4128) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 7.6. Inpatient Pharmacy Technician Services

~~4128. Notwithstanding any other provision of this chapter or any other provision of law, a general acute care hospital, as defined in subdivision (a) of Section 1250 of the Health and Safety Code, may implement and operate a program utilizing specially trained pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for patients admitted to the hospital whose orders have previously been reviewed by a licensed pharmacist. A hospital implementing and operating a program pursuant to this section shall meet all of the following requirements:~~

~~(a) The hospital shall conduct a special training program for technicians who perform the checking function that provides the technicians with the same training that a pharmacist would be provided with under paragraph (1) of subdivision (b) of Section 4052.~~

~~(b) The hospital shall conduct a continuous quality improvement program.~~

~~(c) The hospital shall establish and maintain a program utilizing pharmacists to provide clinical services, as described in Section 4052.~~

~~(d) The hospital shall have a current, nonprovisional, nonconditional accreditation from the Joint Commission on the Accreditation of Healthcare Organizations or another nationally recognized accrediting organization.~~

4128. (a) Notwithstanding any other provision of law, a general acute care hospital, as defined in subdivision (a) of Section 1250 of the Health and Safety Code, may implement and operate a program utilizing specially trained pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for patients admitted to the hospital whose orders have previously been reviewed by a licensed pharmacist. The hospital may implement and operate this type of a program if all of the following requirements are met:

(1) The hospital conducts a special training program for technicians who perform the checking function that satisfies the requirements of subdivision (b).

(2) The hospital conducts a continuous quality improvement program that, at a minimum, audits the performance of the specially trained pharmacy technicians at least every three months for the first year, and annually thereafter. A pharmacy technician whose audited accuracy rate falls below 99.8 percent shall not be permitted to check the work of other pharmacy technicians until he or she is requalified pursuant to paragraph (1).

(3) The hospital has a current nonprovisional, nonconditional accreditation from the Joint Commission on the Accreditation of Healthcare Organizations or another nationally recognized accrediting organization.

(4) The hospital pharmacy has been inspected by the board.

(5) The hospital establishes and maintains a program utilizing pharmacists to provide clinical services as described in Section 4052.

(b) The training program required by paragraph (1) of subdivision (a) shall include both didactic and practical

elements, and shall specify requirements to be completed prior to the technician commencing participation in the checking program.

(1) The didactic component of the training shall consist of at least four hours of education covering the following topics:

(A) Information required to be on the label of unit dose or extemporaneous packaging.

(B) Identification of expired or contaminated medications.

(C) The product characteristics that need to be checked for each drug dispensed from the pharmacy.

(D) Special packaging or handling requirements, including refrigeration for certain medications.

(E) Generic names for common name-brand medications.

(F) Recognition and identification of various dosage forms.

(G) Common medical abbreviations and symbols used in pharmacy.

(H) Basic mathematical principles used in pharmacy calculations, including conversions between and within metric, avoirdupois, and apothecary systems.

(2) The practical component of the training shall consist of at least two hours of supervised practice in which the trainee both observes proper checking procedures and performs proper checking procedures under the direct observation of the supervisor.

(c) The board may, by regulation, establish other rules for hospitals utilizing specially trained pharmacy technicians pursuant to this section.

(d) The board may order a hospital to cease activities authorized by this section at any time a hospital fails to satisfy the board that it is capable of continuing to meet the requirements of this section.

(e) Data and records required by this section shall be retained in each participating hospital for at least three years.

(f) Medication that has been placed in floor or ward stock or unit dose distribution systems pursuant to this section shall not be administered to a patient except by a licensed health care provider practicing within the scope of his or her license.

(g) Legal responsibility or liability for errors or omissions that occur as a result of a pharmacy technician checking another pharmacy technician's work pursuant to this section shall be

limited to the holder of the pharmacy permit and the pharmacist in charge.

4128.1. (a) Every hospital utilizing pharmacy technicians to check the work of other pharmacy technicians pursuant to Section 4128 shall maintain for inspection by the board a current list of all pharmacy technicians that have been qualified to perform checking functions.

(b) A pharmacy technician is not eligible to be qualified pursuant to this article unless he or she:

(1) Is currently certified by the Pharmacy Technician Certification Board.

(2) Is currently registered with the board as a pharmacy technician pursuant to Section 4202.

~~SEC. 2.~~

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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ATTACHMENT 3

Date of Hearing: June 14, 2005

ASSEMBLY COMMITTEE ON HEALTH
Wilma Chan, Chair
SB 592 (Aanestad) - As Amended: March 29, 2005

SENATE VOTE : 23-8

SUBJECT : Acute care hospitals: inpatient pharmacy technician services.

SUMMARY : Allows a general acute care hospital to implement a program of allowing specially trained pharmacy technicians to check the work of other pharmacy technicians relating to the filling of floor and ward stock and unit dose distribution for patients whose orders have previously been reviewed by a licensed pharmacist (checking program), under specific requirements. Specifically, this bill :

1) Requires hospitals implementing the checking program to meet all of the following:

   a) Conduct special training program for technicians who perform the checking function, as specified in #2) below;

   b) Conduct quality improvement program that, at a minimum, audits the performance of the specially trained pharmacy technicians at least every three months for the first year, and annually thereafter. Prohibits a pharmacy technician from checking the work of other pharmacy technicians if his or her audited accuracy rate falls below 99.8%, until he or she is requalified, as specified;

   c) Possess current nonprovisional, nonconditional accreditation from the Joint Commission on the Accreditation of Healthcare Organizations or another nationally recognized accrediting organization;

   d) Have the hospital pharmacy inspected by the Board of Pharmacy (Board); and,

   e) Establish and maintain a program using pharmacists to provide clinical services, as specified in existing law.

2) Requires the training program specified in #1) a) to include

didactic and practical elements, and specify requirements to be completed before the technician starts participating in the checking program.

3) Requires the didactic training to consist of at least four hours of education covering topics on label or packaging information, identification of expired or contaminated medications, product characteristics, special packaging or handling requirements, generic names, dosage forms, medical abbreviations and symbols, and basic mathematical principles.

4) Requires the practical component of the training to consist of at least two hours of supervised practice in which the trainee both observes proper checking procedures under the direct observation of the supervisor.

5) Allows the Board to establish other rules, through regulations, for hospitals utilizing the checking program.

6) Allows the Board to order a hospital to stop the checking program at any time a hospital fails to satisfy the Board that it is capable of meeting the requirements of the checking program.

7) Requires a hospital to retain data and records for at least three years.

8) Requires a licensed health care provider practicing within the scope of his or her license to administer to a patient medications placed in floor or ward stock or unit dose distribution systems.

9) Limits legal responsibility or liability for errors or omissions that occur as a result of a checking program to the holder of the pharmacy permit and the pharmacist in charge.

10) Requires a hospital to maintain, for inspection by the Board, a current list of all pharmacy technicians that have been qualified to perform checking functions.

11) Requires a pharmacy technician, to qualify under the checking program, to be currently certified by the Pharmacy Technician Certification Board and registered with the Board.

12) Makes findings and declarations regarding the workload of

pharmacists and the need for pharmacy technicians to perform

specific functions to ease the workload of pharmacists.

EXISTING LAW :

1) Requires pharmacy technicians to be certified by the Board. Allows a pharmacy technician to perform packaging, manipulative, repetitive, or other nondiscretionary tasks, only while assisting, and while under the direct supervision and control of a pharmacist.

2) Requires a pharmacist on duty to be directly responsible for the conduct of a pharmacy technician. Requires any pharmacist responsible for a pharmacy technician to be on the premises at all times, and the pharmacy technician shall be within the pharmacist's view.

3) Requires an applicant for registration as a pharmacy technician to be issued a certificate of registration if he or she is a high school graduate or possesses a general education development equivalent, and meets any one of the following requirements:

   a) Obtains an associate's degree in pharmacy technology;

   b) Completes a course of training specified by the Board; or

   c) Graduates from a school of pharmacy accredited by the American Council on Pharmaceutical Education or a school of pharmacy recognized by the board.

FISCAL EFFECT : Unknown. This bill was approved by the Senate Appropriations Committee pursuant to Senate Rule 28.8.

COMMENTS :

1) PURPOSE OF THIS BILL . According to the California Society of Health System Pharmacists (CSHSP), the sponsor of this bill, California is currently experiencing a shortage of pharmacists. Allowing pharmacy technicians to perform tasks within their training, education, and registration would allow hospital-based pharmacies to provide more clinically based functions with physicians, nurses, and other health care providers. CSHSP points out this bill would significantly

reduce medication related errors and greatly improve the quality of care processes for chronically ill patients receiving treatment in hospitals. CSHSP stresses that this bill is based upon a 2002 collaborative study between the University of California, San Francisco, School of Pharmacy,

Long Beach Memorial Medical Center, and Cedars-Sinai Medical Center, in which the Board authorized an experimental program to evaluate and compare the accuracy between licensed pharmacists and registered pharmacy technicians

2) EXPERIMENTAL PROGRAM . According to background information provided by CSHSP, in 1997, Cedars-Sinai Medical Center (Cedars) and Long Beach Memorial Medical Center (Long Beach) petitioned the Board to grant a waiver of the California Code of Regulations prohibiting board-registered pharmacy technicians to check unit dose cassettes filled by other pharmacy technicians in the inpatient environment. In California, unit dose medication cassettes that are filled by pharmacy technicians must be checked by a pharmacist. When filling a medication cassette with unit dose medications, a technician reads a list of medications (a "fill list") previously verified by a pharmacist, removes the unit dose medication from stock, and places it in a patient's cassette or medication drawer. The pharmacist then verifies the filled cassette against the list to minimize the possibility of errors. Cedars and Long Beach wanted to conduct an experimental program under the direction of the University of California, San Francisco, School of Pharmacy, to compare the accuracy of unit dose medication cassettes checked by pharmacists with those of registered pharmacy technicians. In May 1998, the Board granted the waiver and the experimental program was known as "Evaluating the Use of Board Registered Pharmacy Technicians in a Unit-Dose Drug Distribution System." The report on the experimental program was released in December 2002 and indicated that pharmacists spend one hour per day checking technician-filled medication cassettes, which competes with the increasing demands on pharmacists to provide clinical services and become more involved in medication safety initiatives, in addition to dealing with the increased complexity of hospitalized patients and the pharmacists shortage. The pharmacists and technicians were all aware of the study but not when audits would be conducted. The report revealed that of the 39 pharmacy technician checkers, 161,740 doses were checked and an accuracy rate of over 99.8% was achieved. The program compared this to 29 pharmacists who

checked 35,829 doses and achieved an accuracy rate of over 99.5%.

3) MEDICAL ERRORS. According to a 1999 report by the Institute of Medicine (IOM) entitled "To Err is Human," between 44,000 and 98,000 Americans die each year as a result of all types of medical errors. Medication errors, according to the report, include stocking patient-care units in hospitals with certain full-strength drugs. The report also stated that medication

errors increase with complexity. Complexity in the medication system arises from several sources; including the extensive knowledge and information that are necessary to correctly prescribe a medication regimen for a particular patient; the intermingling of medications of varying hazard in the pharmacy, during transport, and on the patient care units; and the multiple tasks performed by nurses, of which medication preparation and administration are but a few. TOM also estimates that medication-related errors for hospitalized patients cost roughly 2.4 million extra hospital days and $9.3 billion in extra charges for longer stays and additional care per year.

4) WORKFORCE SHORTAGE . According to a study published in December, 2000, by the United States Department of Health and Human Services, "The Pharmacist Workforce: A Study of the Supply and Demand for Pharmacists," the evidence clearly indicates the emergence over the past few years of a shortage of pharmacists. The study found that there has been an unprecedented demand for pharmacists and for pharmaceutical care services, and the factors causing the current shortage are of a nature not likely to abate in the near future without fundamental changes in pharmacy practice and education. Factors causing the shortage include a 44% increase in the number of retail prescriptions dispensed per year in the United States between 1992 and 1999, and a 32% increase in the number of prescriptions filled per pharmacist during the same time period. According to this study, the pharmacist supply in California was at 54 pharmacists per 100,000 population, well below the nationwide average of 68 per 100,000.

California ranks 49th in the nation in the proportion of registered nurses per 100,000 population. The Employment Development Department estimates that California needs 30,000 additional nurses in the next four years and by 2010, there will be a demand for 109,600 nurses. According to the

California Board of Registered Nursing, there are 539 full time-equivalent registered nurses per 100,000 population.

5) OTHER STATES . According to the report on the experimental program, other states, including Washington, Kansas, and Minnesota, currently allow pharmacy technicians to check unit dose medication cassettes.

6) SUPPORT . The supporters point out that California hospitals are experiencing a severe shortage of pharmacists and this bill would allow pharmacists to perform more complex tasks in hospitals. They state that the tasks delegated to pharmacy technicians in this bill can be safely delegated as indicated

by the experimental program at Cedars and Long Beach Hospitals. Cedars-Sinai Health System points out that in a hospital setting, the checking of doses in the pharmacy is performed prior to the medications being delivered to the inpatient units where the nurse again checks the medication to ensure it is correct before giving it to the patient.

7) OPPOSITION . According to the California Nurses Association (CNA), allowing pharmacy technicians to perform the work of pharmacists would put unreasonable and increased load on nurses who are already experiencing enormous pressures in acute care settings. In addition, CNA states this bill would put patients at an increased risk of medication errors. Other opponents believe pharmacists should continue to check the work of pharmacy technicians so that pharmacists do not lose control of pharmacy practices for which pharmacists are legally responsible and to insure that pharmacies are operated at the highest degree of integrity and efficiency.

8) POLICY QUESTIONS . Does the policy proposed in this bill have the potential to worsen medication errors in California hospitals? Will the policy proposed in this bill put more pressure on nurses? Has there been sufficient study of the issue in California to warrant this policy change? Does one nonrandomized study of 29 pharmacists and 39 technicians in two hospitals provide sufficient evidence to support a lower oversight standard in all California hospitals?

9) PRIOR LEGISLATION . SB 393 (Aanestad) introduced in 2003, is substantially similar to the provisions of this bill and would have authorized general acute care hospitals to implement and operate a program using specially trained pharmacy technicians

to check the work of other pharmacy technicians under prescribed conditions and circumstances. This bill did not move out of the Senate.

10) REFERRAL REQUEST . Assembly Committee on Business and Professions requested to hear this bill. Should this bill pass out of this committee, it will be referred to the Assembly Committee on Business and Professions.

REGISTERED SUPPORT / OPPOSITION :

Support

California Society of Health System Pharmacists (sponsor)
Arroyo Grande Community Hospital
California Hospital Association

California Medical Association
California Pharmacists Association
California State Board of Pharmacy
Catholic Healthcare West
Cedars-Sinai Health System
Dominican Hospital
French Hospital Medical Center
Mark Twain St Joseph's Hospital
Mercy Medical Center Redding
Northridge Hospital Medical Center
San Gabriel Valley Medical Center
Scripps Health
Sierra Nevada Memorial Hospital
St. Joseph's Medical Center
Sutter Health

Opposition

California Labor Federation
California Nurses Association
United Food & Commercial Workers

Analysis Prepared by : Rosielyn Pulmano / HEALTH / (916) 319-2097

ATTACHMENT 4

SUPERIOR COURT OF CALIFORNIA
COUNTY OF SACRAMENTO

DATE/TIME : JULY 14, 2005	**DEPT. NO : 16**
JUDGE : JUDY HERSHER	**CLERK : D. AHEE**
REPORTER : NONE	**BAILIFF : J. TRAVIS**
	PRESENT:
CALIFORNIA NURSES ASSOCIATION, **Petitioner,**	**PAMELA ALLEN**
VS. Case No.: 00AS00900	
TERESA BELLO-JONES, in her official capacity, CALIFORNIA BOARD OF VOCATIONAL NURSING AND PSYCHIATRIC TECHNICIANS, et al, **Respondent.**	**JESSICA AMGWERD** **JANICE LACHMAN**

Nature of Proceedings: COURT'S RULING UNDER SUBMISSION

The Court grants CNA's request for a peremptory writ of mandate commanding Respondents to set aside the amended Regulations, and for a permanent injunction enjoining the implementation and enforcement of the amended Regulations. The Court denies CNA's request for declaratory relief in respect to the October 29, 2001, Advice Letter.

Background Facts and Procedure

This case involves challenges to the validity of (I) a formal regulation purportedly expanding the scope of practice of Licensed Vocational Nurses to include the administration of intravenous medications in certain clinical settings; and (II) alleged "underground regulations" which expand the scope of authority of Licensed Vocational Nurses to include performance of registered nursing functions of patient assessment and access to central intravenous lines.

Prior to 1999, California regulations governing the practice of Licensed Vocational Nurses ("LVNs") did not permit LVNs to administer medication

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BY: D. AHEE
Deputy Clerk

intravenously. In or about June 1999, the Board of Vocational Nursing and Psychiatric Technicians ("Board") recommended amending the regulations to permit specially trained LVNs to administer intravenously substances which are routinely given during the course of hemodialysis, pheresis, and blood bank procedures. At a meeting on November 16, 2001, the Board adopted proposed changes to the California Code of Regulations, title 16, sections 2542, 2542.1, 2547, 2547.1 (the "Regulations"), which would have allowed LVNs to administer specified intravenous medications in hemodialysis, pheresis and blood bank settings under certain conditions. On February 28, 2002, the Board submitted the amended regulations to the OAL for review and approval.

On April 12, 2002, OAL disapproved the Board's proposed regulatory action based on the following three grounds: (1) the proposed regulations enlarge the scope of practice of the LVN and appear to be inconsistent with the Vocational Nursing Practice Act; (2) the Regulations require that a registered nurse or licensed physician be in the "immediate vicinity" of the LVN when the procedure is performed, but the term "immediate vicinity" was not defined and was found to be susceptible to differing interpretations by affected persons; and (3) the micro-cassette recordings of the public hearing included in the rulemaking file was mostly inaudible and there was no transcript or minutes in the file. Nothwithstanding OAL's denial, OAL's Decision of Disapproval of Regulatory Action included the following statement:

> "We realize that Business and Professions Code section 2860.5 was last amended in 1974, and that modern medical technology has advanced considerably since then. Old definitions and understandings may need to be changed if medical and nursing practice have evolved to the point where professionals in the field would consider such medications as an integral component or ingredient of intravenous fluids. If the Board can supplement the record with facts, studies, expert opinion or other information that tends to show this evolution in nursing practice, these regulations could be resubmitted within 120 days of receipt of this decision for further OAL review and consideration."

On June 5, 2002, in response to the OAL's Decision of Disapproval, the Board proposed modifications to the Regulations and added documents to the

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rulemaking record for the proposed regulatory amendments. To address OAL's other concerns, the Board relied upon a legal memorandum entitled Authority for Intravenous Therapy Regulatory Amendment, it modified the text of the Regulations to provide that the definition of "immediate vicinity" shall be set forth in the standardized procedures of the facility, and to address the issue of missing or defective documents, the Board prepared minutes of the public hearing of April 17, 2001. After giving notice of the proposed modifications to the Regulations, the Board received comments and prepared a Supplement to Final Statement of Reasons.

On June 28, 2002, the Board adopted proposed amendments to sections 2542, 2542.1, 2547, and 2547.1 of the California Code of Regulations. As before, the proposed amendments would allow LVNs who are Board-certified in intravenous therapy to administer "specified intravenous medications in hemodialysis, pheresis, and blood bank procedures" under certain conditions. On December 13, 2002, the Board submitted its proposed Regulations to the Office of Administrative Law. The amended Regulations were approved by the OAL on January 29, 2003.

On February 24, 2003, Petitioner CNA filed a Complaint for Declaratory and Injunctive Relief against four defendants: Teresa Bello-Jones, the Board, Ruth Ann Terry, and the California Board of Registered Nursing. CNA's Complaint challenged the regulations permitting LVNs to administer medications intravenously. The Complaint also challenged two "underground regulations" allegedly promulgated by the Board in a October 29, 2001, letter to the California Dialysis Council.

On March 21, 2003, CNA filed a First Amended Complaint. A demurrer to the First Amended Complaint was sustained with leave to amend on June 13, 2003.

On June 22, 2003, CNA filed a Second Amended Complaint against the original four defendants. Defendants Ruth Ann Terry and the California Board of Registered Nursing filed a demurrer to the Second Amended Complaint, which was sustained without leave to amend on October 9, 2003. Defendants Ruth Ann Terry and the California Board of Registered Nursing were dismissed with prejudice on October 15, 2003.

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In or about April 2004, CNA requested a preliminary injunction to halt implementation of the Regulations. CNA's request for preliminary injunctive relief was denied.

On January 20, 2005, CNA filed its Petition for Writ of Mandamus and Third Amended Complaint for Declaratory and Injunctive Relief to Invalidate and Enjoin Regulatory Action in Excess of Statutory Authority (the "Petition").

Discussion

CNA brings this Petition to prevent what it claims is an unauthorized expansion of the scope of practice of LVNs to permit LVNs to perform various nursing functions heretofore exclusively within the authority and scope of registered nurses.

CNA's Petition alleges three causes of action. The First Cause of Action, for Writ of Mandate, alleges that the Regulations authorizing LVNs to administer IV medications are invalid for failure to comply with the Administrative Procedures Act. The Second Cause of Action seeks temporary and permanent injunctive relief to enjoin the Regulations and thereby prohibit the administration of IV medications by LVNs. The Third Cause of Action seeks a declaratory judgment that the Board lacks the authority to amend the Regulations to expand the scope of LVN practice to include the administration of IV medications. The Third Cause of Action for declaratory relief also challenges an October 29, 2001, Advice Letter from the Board to the California Dialysis Council on the grounds: (i) the letter constitutes an "underground regulation" not enacted in conformance with the Administrative Procedures Act; and (ii) the Board's advice in the letter that LVNs are permitted central line access and to perform assessments on hemodialysis patients is contrary to existing law.

A. Standard of Review

When a court inquires into the validity of a quasi-legislative administrative regulation, the scope of review is limited. (*Cal. Assn. of Psychology Providers v. Rank* (1990) 51 Cal.3d 1, 11.) The court's task is to determine whether the regulation is (1) within the scope of the authority conferred by the statute, and

(2) reasonably necessary to effectuate the purposes of the statute. (*Ralphs Grocery Co. v. Reimel* (1968) 69 Cal.2d 172, 175; *Agricultural Labor Relations Bd. v. Superior Court* (1976) 16 Cal.3d 392, 411.)

Judicial review of quasi-legislative acts generally consists of an examination of the proceedings before the agency to determine whether its actions were arbitrary, capricious, or entirely lacking in evidentiary support, or whether the agency failed to follow the procedures and give the notices required by law. (*Rank, supra*, at p.11.)

When, however, a regulation is challenged as inconsistent with the terms or intent of the authorizing statute, the standard of review is different. (*Id.*) In determining whether a regulation is within the scope of the authority conferred by a statute, a court does not defer to an agency's view because the court, not the agency, has final responsibility for the interpretation of the law under which the regulation was issued. (*Yamaha Corp. v. State Bd. of Equalization* (1998) 19 Cal.4th 1, 11 fn.4.) If the court determines that a challenged administrative action was not authorized by or is inconsistent with acts of the Legislature, that action is void. (*American Ins. Assn. v. Garamendi* (2005) 127 Cal.App.4th 228, 236; *see also* Gov. Code §§ 11350, 11342.1, 11342.2.)

The California Supreme Court has summarized the standard courts must apply when reviewing an agency's interpretation of a statute as follows:

> "Courts must, in short, independently judge the text of the statute, taking into account and respecting the agency's interpretation of its meaning, of course, whether embodied in a formal rule or less formal representation. Where the meaning and legal effect of a statute is the issue, an agency's interpretation is one among several tools available to the court. Depending on the context, it may be helpful, enlightening, even convincing. It may sometimes be of little worth. Considered alone and apart from the context and circumstances that produce them, agency interpretations are not binding or necessarily even authoritative. To quote the statement of the Law Revision Commission in a recent report, 'the standard of judicial review of an agency interpretation of law is the independent judgment of the court, giving deference to the determination of the

> agency appropriate to the circumstances of the agency action.'" (*Yamaha, supra*, at p.8 [citations omitted].)

B. Were the Amended Regulations Adopted in Accordance with the Law?

According to CNA, the amended Regulations exceed the scope of the Board's authority under the Vocational Nursing Practice Act (Bus. & Prof. Code §§ 2840 et seq.). Specifically, CNA contends the Regulations violate section 2860.5(c) of the Act. Thus, the Court is called upon to interpret the intent of that statute.

To determine legislative intent, the Court turns first to the actual language of the statute. If the words of the statute are clear, a court should not add to or alter them to accomplish a purpose that does not appear on the face of the statute or from its legislative history. (*Herman v. Los Angeles County Metropolitan Transportation Authority* (1999) 71 Cal.App.4th 819, 826.) But if the meaning of the words is not clear, courts must take the second step and refer to the legislative history. The final step, which should be taken only if the first two steps fail to reveal clear meaning, is to apply reason, practicality, and common sense to the language at hand. (*Id.*) The Court applies these rules of construction to the facts and the statute at issue here.

Business and Professions Code section 2860.5 sets forth the scope of practice of LVNs. It provides:

> "A licensed vocational nurse when directed by a physician and surgeon may do all of the following:
>
> (a) Administer medications by hypodermic injection.
>
> (b) Withdraw blood from a patient, if prior thereto such nurse has been instructed by a physician and surgeon and has demonstrated competence to such physician and surgeon in the proper procedure to be employed when withdrawing blood, or has satisfactorily completed a prescribed course of instruction approved by the

board, or has demonstrated competence to the satisfaction of the board.

(c) Start and superimpose intravenous fluids if all of the following additional conditions exist:

(1) The nurse has satisfactorily completed a prescribed course of instruction approved by the board or has demonstrated competence to the satisfaction of the board.

(2) The procedure is performed in an organized health care system in accordance with the written standardized procedures adopted by the organized health care system as formulated by a committee which includes representatives of the medical, nursing, and administrative staffs. "Organized health care system," as used in this section, includes facilities licensed pursuant to Section 1250 of the Health and Safety Code, clinics, home health agencies, physician's offices, and public, or community health services. Standardized procedures so adopted will be reproduced in writing and made available to total medical and nursing staffs."

The Board contends that under the plain language of the statute, the phrase "intravenous fluids" must be construed to include "medications that can be administered intravenously." According to the Board, if the Legislature had intended to exclude "medications" from the definition of "intravenous fluids," this would have been clearly stated in the statute. Because it was not, the Board contends, the Legislature must have intended the definition of "intravenous fluids" to have a broad meaning to allow for the expanding nature of the LVN profession. Therefore, the Board argues, the amended Regulations are within the scope of the authority conferred by the statute and it is unnecessary to refer to the legislative history of the statute.

The Court, however, does not find the statutory language to be free of ambiguity. To the contrary, the Legislature's use of the word "medications" in subsection (a) but not in subsection (c) renders the statute ambiguous on its

face. Was subsection (a) added to limit the circumstances under which LVNs may administer medication to hypodermic injections, or merely to clarify that LVNs shall be authorized to give hypodermic injections containing medications in addition to administering intravenous fluids?

The Court is unable to answer this question by looking at the face of the statute. Neither the term "intravenous fluid," nor the term "medication" is defined by the Vocational Nursing Practice Act, so the Court must resort to the "ordinary, everyday" meaning of such terms. (*Herman, supra*, at p.826.) The Board contends that the ordinary, everyday meaning of the term "fluid" is a substance tending to flow or conform to the outline of its container, and that the term "intravenous fluids" includes any fluid that can be administered intravenously, including "fluids" of medications. The Board further contends that the ordinary, everyday meaning of the word "medication" includes substances used as a remedial treatment of a mental or bodily disorder, and that, under this definition, nutrients, electrolytes, and other fluids are all "medications." (*See* AG 601-02.)

However, as documented in the OAL's Decision of Disapproval, medical dictionaries and reference sources generally distinguish between the terms "intravenous fluids" and "medications" by separating the words by an "and," "or," a comma, or other distinguishing words (e.g., "The label of each container of fluid or medication . . . ."). This suggests that, at least in the medical community, the term "intravenous fluids" does not necessarily include "medications." (*See* AG 575-76.)

In its Supplement to Final Statement of Reasons, the Board contended that LVNs were authorized to administer medications intravenously by section 2860.5(a) because the term "hypodermic injection" includes "intravascular" injections. (AG 643.) The Court is not persuaded by this argument. First, it is dubious that the ordinary, everyday meaning of a "hypodermic injection" in 1974 included intravascular injections. (*See, e.g.*, AG 575, 907.) Second, this interpretation renders the statute absurd in that it would authorize an LVN to administer *medications* intravenously without condition, but would authorize LVNs to administer *fluids* intravenously only if the nurse has satisfactorily completed a prescribed course of instruction and demonstrated competence and

the procedure is performed in an organized health care system in accordance with written standardized procedures. (*See* Bus. & Prof. Code § 2860.5(a), (c).)

Similarly, the Court is unable to rely on the principle of statutory construction that a specific provision relating to a particular subject governs as against a general provision, (*People v. Superior Court* (2002) 28 Cal.4th 798, 809), because it is unclear from the face of the statute whether subsection (a) was intended as a specific limitation on when LVNs may administer medications, or as general authorization for them to administer hypodermic injections.

Construing the statute in the context of the overall statutory scheme is similarly unavailing. (*CEJA v. J.R. Wood, Inc.* (1987) 196 Cal.App.3d 1372, 1375 [holding that a statute is required to be construed in context, keeping in mind the nature and purpose of the statutory scheme of which it is a part].)

It is true that the statutory framework authorizes unlicensed hemodialysis technicians to administer medications intravenously under some circumstances. (*See* Health & Safety Code § 1794.14(d); Bus. & Prof. Code §§ 1247.2, 1247.3.) The Board contends that because the Legislature authorized unlicensed technicians to administer medications, it also must have intended for Licensed Vocational Nurses to be authorized to do so. However, this does not necessarily follow. First, the Hemodialysis Technician Training Act is a wholly unrelated statute; there are any number of reasons why the Legislature might permit unlicensed hemodialysis technicians to administer medications in hemodialysis settings but preclude Licensed Vocational Nurses from doing so. Second, the Hemodialysis Technician Training Act was enacted more than 13 years after AB 3618. Thus, even if the Hemodialysis Technician Training Act could be construed as evidence that the Legislature was willing to permit personnel other than licensed RNs to administer medications intravenously in 1987, this sheds no light on what the Legislature intended when it enacted AB 3618 in 1974.

Finally, in response to the argument that the Legislature would have expressly prohibited intravenous medications if it had so intended, the Court notes that one could just as easily assert that the absence of authorization to administer intravenous medications is conspicuous and suggests the Legislature did not intend LVNs to have such authority.

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In sum, the Court is unable to resolve these conflicts and therefore concludes the statute is ambiguous.

Case law holds that if the meaning of the words of a statute are not clear, the second step of statutory interpretation is to refer to the legislative history. (*Herman v. Los Angeles County Metropolitan Transportation Authority* (1999) 71 Cal.App.4th 819, 826.) In this case, the legislative history shows that section 2860.5(c) was not intended to include medications.

Section 2860.5 was last amended in 1974 by AB 3618. The April 4, 1974, proposed version of subsection 2 of the bill provided:

> Sec. 2. Section 2860.5 of the Business and Professions Code is amended to read:
>
> A licensed vocational nurse when directed by a physician and surgeon may do all of the following:
>
> (a) Administer medications by hypodermic injection.
> . . .
> (c) *Start and superimpose intravenous fluids, and administer medications, as part of intravenous therapy. The above may only be done if prior thereto such nurse has completed a prescribed course of instruction by the board and demonstrated competence and demonstrated understanding of the effect of such medications and appropriate action to be taken if untoward reaction occurs.* (AG 923-924.)

CNA opposed the April 4, 1974, version of AB 3618 because, among other reasons, CNA wanted "to strike the LVNs authority to 'administer medications'" as part of intravenous therapy. (AG 926.) The Legislature subsequently amended AB 3618 on June 5, 1974, specifically to delete the language that would have given LVNs the authority to administer medications as part of intravenous therapy. (AG 921-22, 924-25.) As amended, the bill provided:

> Section 1. Section 2860.5 of the Business and Professions Code is amended to read:

2860.5. A licensed vocational nurse when directed by a physician and surgeon may do all of the following:

(a) Administer medications by hypodermic injection.

. . .

(c) Start and superimpose intravenous fluids, ~~and administer medication, as part of intravenous therapy. The above may only be done if prior thereto such nurse has completed a prescribed course of instruction by the board and demonstrated competence and demonstrated understanding of the effect of such medications and appropriate action to be taken if untoward reaction occurs~~ if all of the following additional conditions exist:

(1) The nurse has satisfactorily completed prescribed course of instruction approved by the board or has demonstrated competence to the satisfaction of the board.

(2) The procedure is performed in an organized health care system in accordance with written standardized procedures adopted by the health care system as formulated by the committee which includes representatives of the medical, nursing, and administrative staffs. . . ." (AG 924-925.)

It thus appears that the Legislature amended the bill to delete the language that would have included administration of intravenous medications within the LVN scope of practice. The amended bill was passed by the Assembly and the Senate and signed into law by the Governor on September 23, 1974. (AG 929.)

The general rule is that when the Legislature has rejected a specific provision which was part of an act when originally introduced, the law as enacted should not be construed to contain that provision.[1] (*Ventura v. City of San Jose*

[1] This rule has some exceptions. For instance, it does not apply if the specific language is replaced by general language that includes the specific instance. (*California Ass'n of Psychology Providers v. Rank* (1990) 51 Cal.3d 1, 17-18.) The example given in *Rank* is that if a bill were introduced dealing with "teachers' salaries in Los Angeles County," then amended to deal with "teachers' salaries" generally, the court would not construe it to apply to all counties except Los Angeles. (*Id.*) This exception might apply here if the term "intravenous fluids" were construed to

(1984) 151 Cal.App.3d 1076, 1080.) Accordingly, this Court concludes that because the Legislature deleted the language authorizing LVNs to administer medications intravenously, the statute cannot be construed to contain that provision.

The Board's early interpretation of the statute also appears to support the conclusion that LVNs were not authorized to administer IV medications. In a Notice from the Board issued on or about March 10, 1978, the Board stated the following:

> "It has been brought to the attention of the Board that there may be Licensed Vocational Nurses employed in facilities who are administering intravenous medications. This notice is being sent in order to reach those facilities that are permitting the L.V.N.s to perform this illegal procedure.
>
> "The regulations define those intravenous solutions that L.V.N.s are permitted to start and superimpose. Medications are not included since this was not the intent of the law. Therefore, it must be pointed out that the L.V.N. is not permitted by law to administer intravenous medications, add medications to an intravenous solution, or start and/or superimpose solutions that contain medications." (Declaration of Pamela Allen, Ex. A-1.)

The Board has attempted to explain its 1978 interpretation of "the law" as a reference to the Board's then-existing regulations, which excluded medications from the definition of intravenous fluids, rather than a reference to the statute itself. The Court finds this argument unpersuasive in light of the fact that elsewhere in the Notice, the Board appeared to distinguish "the law" (i.e., the statute) from its regulations: "The Board is concerned that Licensed Vocational

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include "medications." As discussed above, there is no indication that the Legislature interpreted "intravenous fluids" in such a manner, or that the Legislature deleted the reference to IV medications because it believed such words were superfluous. To the contrary, the only evidence suggests the reference to IV medications was deleted in response to objections by CNA that LVNs should not be authorized to administer medications as part of IV therapy. Accordingly, the Court concludes that the exception discussed in *Renk* does not apply in this case.

Nurses practice within the scope of the law and regulations . . . ." If "law" were intended to encompass the Board's regulations, this latter reference to "regulations" would have been superfluous.

Subsequent legislative attempts to interpret or amend section 2860.5 also appear to support the Court's interpretation. In 1980, Assemblyman Alatorre requested a formal opinion from the Legislative Counsel of California asking the specific question, "May the Board of Vocational Nurse and Psychiatric Technician Examiners authorize, by regulation, licensed vocational nurses to administer medications by intravenous injection?" (AG 905-907.) The response by Legislative Counsel provides, in relevant part:

> "We think it is clear that the Legislature has, by the provisions of Section 2860.5, limited licensed vocational nurses, insofar as the administration of medications by injection are concerned, to that of the hypodermic injection method and has limited the use of intravenous method to that of the starting and superimposing of intravenous fluids under specified conditions.
>
> "Thus, a regulation of the [BVNPT] which would authorize licensed vocational nurses to administer medications by intravenous injection would be authority which is beyond that authorized by Section 2860.5 and, as such, would be invalid." (*Id.*)

While Opinions of the Legislative Counsel, like opinions of the Attorney General, are not binding, the California Supreme Court has held that in the absence of controlling authority, they are persuasive. (*Cal. Assn. of Psychology Providers v. Rank* (1990) 51 Cal.3d 1, 17; *see also Eu v. Chacon* (1976) 16 Cal.3d 465, 470 ["Although a legislative expression of the intent of an earlier act is not binding on the courts . . . that expression may properly be considered together with other factors in arriving at the true legislative intent existing when the prior act was passed."].)

In response to the Legislative Counsel's Opinion, Assemblyman Alatorre introduced legislation (AB 642) in the 1981-82 legislative session that would have "authorize[d] a licensed vocational nurse to start and superimpose intravenous fluids containing medications under specified conditions." (AG 908-910, 915-

918.) AB 642 was sponsored by the Board. In a January 22, 1983 letter to hospital administrators, the Board stated:

> "The Board of Vocational Nurse and Psychiatric Technician Examiners sponsored AB 642 authored by Assemblyman Richard Alatorre in the 1981-82 legislative session. This measure would have expanded the scope of Practice of Licensed Vocational Nurses and authorized them to administer certain intravenous medications after successful completion of a course of instruction approved by the Board. This legislation failed in the Senate Finance Committee." (Declaration of Pamela Allen, Ex. A-3.)

The Legislature's failure to enact an amendment to a statutory scheme generally provides little guidance on the issue of legislative intent. (*American Ins. Assn. v. Garamendi* (2005) 127 Cal.App.4th 228, 246.) This is because the Legislature's failure to amend a statute evokes conflicting inferences. (*Id.*) However, when determining whether an administratively promulgated rule is consistent with controlling legislation, legislative rejection of an authorizing statute may prove more persuasive. (*Id.*) The Legislature is presumed to act with knowledge of an agency's administrative interpretation of the statute, and it is reasonable to assume the Legislature would have taken corrective action had it disagreed with the existing administrative interpretation. (*Jones v. Pierce* (1988) 199 Cal.App.3d 736, 745-46.) Thus, the Legislature's failure to change the law lends credence to the Board's administrative construction at the time AB 642 was rejected. Moreover, the Board's attempt to obtain legislative amendment of the governing statute can be construed as an implicit admission that legislative authorization was needed. (*Garamendi, supra*, at p.246.)

Respondent Board argues that notwithstanding this legislative history, the Court should defer to the Board's current interpretation of the statute. The Board cites cases holding that where an agency is charged with enforcing a statute, its interpretation of the statute should be entitled to "great weight." (Opposition, p.11 [citing *Lusardi Construction Co. v. Calif. Occupational Safety & Health App. Bd.* (1991) 1 Cal.App.4th 639, 645; *Pacific Legal Foundation v. Unemployment Ins. Appeals Bd.* (1981) 29 Cal.3d 101, 111; *Sheyko v. Saenz* (2002) 112 Cal.App.4th 675, 686].) The Board contends the Court should defer to the agency's interpretation even if such interpretation is not consistent with

the agency's prior interpretation. The Board cites cases holding that "[e]ven when an agency adopts a new interpretation of a statute and rejects an old, a court must continue to apply a deferential standard of review. . . ." (*See, e.g., Henning v. Industrial Welfare Commn.* (1988) 46 Cal.3d 1262, 1270.) In the abstract, this appears to be a correct statement of the law. However, there is an exception to this general rule.

As held by the Supreme Court in the *Henning* case, which was relied upon by the Board: "When as here the construction in question is not 'a contemporaneous interpretation' of the relevant statute and in fact 'flatly contradicts the position which the agency had enunciated at an earlier date, closer to the enactment of the . . . statute[,]' it cannot command significant deference." (*Id.* at p.1278.) This point was reiterated by the Supreme Court in *Yamaha Corp. of America v. State Board of Equalization* (1998) 19 Cal.4th 1, 14, which held that the weight given to an agency's interpretation of a statute "will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade . . . ." (*See also Brewer v. Patel* (1993) 20 Cal.App.4th 1017, 1022 [finding no reason to defer to Labor Commissioner's interpretation of regulation where interpretation was contrary to plain meaning of statute and inconsistent with Commissioner's own prior interpretation of the rule]; *Whitcomb Hotel, Inc. v. California Emp. Comm.* (1944) 24 Cal.2d 753, 757 ["At most administrative practice is a weight in the scale, to be considered but not to be inevitably followed . . . ."].)

In this case, the evidence shows that the Board's current interpretation of the statute is of recent origin, and is not consistent with the Board's earlier interpretation of the statute, which the Board made much closer in time to when the statute was enacted. Therefore, the Board's interpretation is not entitled to the deference that it otherwise would be due.

In any event, whatever the force of administrative construction, relevant case law establishes that final responsibility for interpretation of the law rests with the court. The Court concludes that the Board's interpretation of section 2860.5 is erroneous. As construed by this Court, section 2860.5 prohibits the Board to adopt a regulation authorizing LVNs to administer intravenous medications. Therefore, the amendments to California Code of Regulations, title

16, sections 2542, 2542.1, 2547, and 2547.1, allowing LVNs to administer IV medications must be enjoined as inconsistent with the Vocational Nursing Practice Act.

C. Does the Board's October 29, 2001, Letter to the California Dialysis Council Constitute an Underground Regulation?

On October 29, 2001, the Board responded by letter to an "inquiry" from the California Dialysis Council ("CDC") asking whether LVNs were authorized to initiate dialysis via a central line catheter and to perform patient assessments for the purposes of determining treatment. In its letter, the Board stated that LVNs "are permitted central line access," and that LVNs "can perform basic assessment, or data collection." There is no dispute that these interpretative statements were not adopted in accordance with the APA procedures. Thus, CNA correctly contends that if the interpretations qualify as "regulations" within the meaning of Government Code § 11342.6, the regulations are invalid. (*California Advocates for Nursing Home reform v. Bonta* (2003) 106 Cal.App.4th 498, 507.)

The Court is not persuaded that the Board's statement in the October 29 letter that "LVNs are permitted central line access" constitutes a regulation subject to the APA. The APA defines "regulation" to include "every rule, regulation, order, or standard of general application or the amendment, supplement, or revision of any rule, regulation, order, or standard adopted by any state agency to implement, interpret, or make specific the law enforced or administered by it, or to govern its procedure." (Gov. Code § 11342.600.) A regulation subject to the APA has two principal identifying characteristics. First, the agency must intend its rule to apply generally, rather than in a specific case. Second, the rule must "implement, interpret, or make specific the law enforced or administered by [the agency], or . . . govern [the agency's] procedure." (*Bonta, supra*, at pp.506-07 [citing *Tidewater Marine Western, Inc. v. Bradshaw* (1996) 14 Cal.4th 557, 571].)

CNA apparently contends that the Board's statement constitutes a "regulation" because it appears to conflict with a June 23, 1993, letter from the Board stating that LVNs may change site dressings but that "[n]o other procedures or manipulation of central lines are permitted." (Declaration of

Pamela Allen, Ex.A-4.) However, the June 23 letter appears to have been responding to a question about bolus or "push" administration into central lines and the language must be read in this context. Moreover, section 2860.5 expressly authorizes LVNs to "start and superimpose intravenous fluids" if certain conditions are met, and does not limit LVNs to accessing secondary infusion lines. Accordingly, the Court interprets the statement in the Board's October 29 letter as a statement of existing law and not as a new "regulation" within the meaning of the APA.

Similarly, the Court is not persuaded that the Board's statement in the October 29 letter that "the LVN can perform basic assessment or data collection" is an underground regulation. The letter merely reiterates what Regulation 2518.5 already provides, namely, that the scope of LVN practice includes "basic assessment (data collection)." (*See* 16 C.C.R. § 2518.5.)

The statements in the Board's October 29 letter do not constitute underground regulations.

D. Conclusion

The Court finds that the amended Regulations must be set aside because the Regulations are not within the scope of the authority conferred by the statute.

Accordingly, the Court grants CNA's request for a peremptory writ of mandate commanding Respondents to set aside the Regulations, and for a permanent injunction enjoining the implementation and enforcement of the Regulations. Respondents shall file a return to the peremptory writ of mandate within 30 days after it is served on them describing what steps they have taken to comply with the writ. The Court denies CNA's request for declaratory relief in respect to the October 29, 2001, Advice Letter.

CNA is directed to prepare a formal judgment, attaching the Court's ruling as an exhibit, and a writ of mandate consistent with the ruling; submit them to opposing counsel for approval as to form; and thereafter submit them to the Court for signature and entry of judgment in accordance with Rule of Court 391.

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and all state and local rules.

Dated: July 14, 2005

Judy Hersher,
Judge of the Superior Court
State of California

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Superior Court of California, Sacramento

BY: D. AHEE, Deputy Clerk

CASE NUMBER: 00A500900 DEPARTMENT: 16
CASE TITLE: CNA V. BELLO JONES
PROCEEDINGS: COURTS RULING UNDER SUBMISSION

CASE NUMBER: 00AS00900 **DEPARTMENT: 16**
CASE TITLE: CNA V. BELLO JONES
PROCEEDINGS: COURTS RULING UNDER SUBMISSION

CERTIFICATE OF SERVICE BY MAILING
(C.C.P. SEC 1013QA(3))

I, the Clerk of the Superior Court of California, County of Sacramento, certify that I am not a party to this cause, and on the date shown below I served the foregoing MINUTE ORDER by depositing true copies thereof, enclosed in separate, sealed envelopes with the postage fully prepaid, in the United States Mail at Sacramento, California, each of which envelopes was addressed respectively to the persons and addressed shown. I, the undersigned deputy clerk, declare under penalty of perjury that the forgoing is true and correct.

Dated: July 14, 2005

D. Ahee, Deputy Courtroom Clerk

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Legal Department
Pamela Allen
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ATTACHMENT 5

CALIFORNIA NURSES ASSOCIATION v. SCHWARZENEGGER, et al.
Case No. 04CS01725.

1:30 p.m. 05/27/2005. Hearing on Petition for Writ of Mandamus.

COURT'S RULING UNDER SUBMISSION: Petition granted.

I.

The parties before the Court are the Petitioner California Nurses Association ("CNA"); Respondent California Department of Health Services ("DHS"); Respondent Arnold Schwarzenegger, Governor of the State of California; Respondent Kim Belshe, Secretary of the California Health and Human Services Agency; Respondent Sandra Shewry, Director of the California Department of Health Services; and Intervenor the California Hospital Association ("CHA").

Petitioner's First Amended Petition for Writ of Mandamus and Complaint for Declaratory and Injunctive Relief (the "Petition") seeks a writ of mandate invalidating Emergency Regulations adopted by DHS on November 12, 2004 (DHS File No. R-01-04E), and March 3, 2005 (OAL File No. 05-0303-04EE). The subject of the Emergency Regulations is a "nurse-to-patient staffing ratio" regulation compelled by legislation sponsored by CNA and enacted in 1999 (AB 394, codified at Health & Safety Code § 1276.4). The nurse-to-patient staffing ratio regulation had been adopted by the DHS after a comprehensive three-year rulemaking proceeding, and had been in operation only since January 1, 2004. Nevertheless, on November 12, 2004, DHS adopted the initial Emergency Regulation, which amended key provisions of the nurse-to-patient staffing ratio regulation, including postponing until January 1, 2008, a required step-down of the ratio for medical/surgical units from 1:6 to 1:5 that was set to take effect on January 1, 2005. On March 3, 2005, this Court tentatively ruled that Petitioner was likely to prevail on its claim that the November 12, 2004 Emergency Regulation (i) exceeded the scope of authority delegated to DHS by the Legislature; (ii) was arbitrary, capricious, and an abuse of discretion; and (iii) was not adopted in the manner required by law. The Court tentatively ruled that the November 12 Emergency Regulation would be enjoined. That same day, DHS adopted the second Emergency Regulation, which was identical in content and format to the original Emergency Regulation, which the Court had tentatively found unlawful. The original Emergency Regulation was set to expire by operation of law on March 14, 2005. On March 14, 2005, this Court issued its orders preliminarily enjoining both Emergency Regulations pending final disposition of the Petition.

The Court is now asked to decide the merits of the Petition. Specifically, Petitioner alleges nine causes of action: Unconstitutional Delegation of Quasi-Legislative Authority [First Cause of Action]; Writ of Mandate for Violation of Administrative Procedures Act [Second, Seventh and Ninth Causes of Action]; Regulation Inconsistent with Authorizing Statute [Third and Sixth Causes of Action];

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Bad Faith -- Breach of Mandatory Duty -- Abuse of Discretion [Fourth Cause of Action]; Unauthorized Emergency Regulations [Fifth Cause of Action]; and Declaratory Relief [Eighth Cause of Action]. In essence, CNA first argues that the Emergency Regulations are invalid because they (i) exceed the scope of authority conferred to DHS by the Legislature; (ii) are not reasonably necessary to effectuate the purposes of the statute; and (iii) would, if permitted to stand, violate the constitutional principle of separation of powers. Second, CNA argues that the Emergency Regulations are invalid because the decision to adopt an "emergency" regulation is not supported by the findings, and the findings are not supported by the evidence. CNA seeks a peremptory writ of mandate commanding respondents to set aside each of the Emergency Regulations and to restore, recognize and enforce the original staffing regulation (No. R-37-01), as well as injunctive and declaratory relief.

As discussed more fully below, the Court finds that a peremptory writ of mandate should issue commanding respondents to set aside each of the Emergency Regulations on the grounds that (i) the regulations are not within the scope of the authority conferred by the statute; (ii) there is not substantial evidence to support the determination that the regulations are reasonably necessary to effectuate the purposes of the statute; and (iii) DHS abused its discretion and failed to follow the procedures established by law in determining that the regulations were necessary for the immediate preservation of public health and safety.

II.
Facts and Procedure

A. Introduction

In 1999, CNA sponsored AB 394 to (1) require the DHS to adopt regulations specifying nurse-to-patient ratios for general acute care hospitals, acute psychiatric hospitals and special hospitals; (2) to require those hospitals to adopt written policies and procedures for nursing staff training; and (3) to prohibit such hospitals from assigning unlicensed personnel to perform nursing functions in lieu of a registered nurse. (CNA 297-301.) In October 1999, the legislature passed AB 394 and it was adopted into law, adding section 1276.4 to the Health and Safety Code. In adopting the new bill, the Legislature declared that the accessibility and availability of nurses is essential "to ensure the adequate protection of patients in acute care settings." (Health & Safety Code § 1276.4.) Thus, AB 394 directs DHS to "adopt regulations that establish minimum, specific, and numerical" nurse-to-patient ratios for those in acute care hospital units.

B. History of Nurse Staffing Ratios

AB 394 is the first nurse-to-patient acute care staffing ratio law in the United States. However, the history of nurse staffing ratios predates AB 394 by many years. The history of AB 394 arguably can be traced back as far as 1973-74. (January 13, 2005, Declaration of Vicki Bermudez, ¶ 9.) During the 1973-74 legislative session, the CNA's "Proposed New Legal Definition of Nursing" became the framework for AB 3124, which

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amended Business and Professions Code section 2725 (the "Nursing Practice Act") to amplify and define the role of the registered nurses in the provision of healthcare. (*Id.*) Business and Professions Code section 2725 explicitly recognizes the existence of overlapping functions between physicians and registered nurses and permits additional sharing of functions within organized health care systems that provide for collaboration between physicians and registered nurses. (Bus. & Prof. Code § 2725.) The statute defines the practice of nursing to mean those functions, including basic health care, that help people cope with difficulties in daily living that are associated with their actual or potential health or illness problems or the treatment thereof, and that require a substantial amount of scientific knowledge or technical skill, including "[d]irect and indirect patient care services." (January 13, 2005, Declaration of Vicki Bermudez, ¶ 10.)

Subsequent to adoption of the Nursing Practice Act, DHS adopted a regulation establishing "Standards of Competent Performance" for registered nurses. (*See* 16 CCR § 1443.5.) The Standards of Competent Performance provide that a registered nurse shall be considered competent when he/she consistently demonstrates the ability to transfer scientific knowledge from social, biological and physical sciences in applying the nursing process, as demonstrated in a number of circumstances. According to CNA, the nursing process is the process used to organize and deliver appropriate nursing care. (January 13, 2005, Declaration of Vicki Bermudez, ¶ 10.) Under the statute and regulations, registered nurses ("RNs") are required to (1) formulate a nursing diagnosis through observation of the client's physical condition and behavior and interpretation of information obtained from the client and others; (2) formulate a care plan, in collaboration with the client, which ensures that direct and indirect nursing care services provide for the client's safety, comfort, hygiene, and protection, and for disease prevention and restorative measures; (3) evaluate the effectiveness of the care plan through observation of the client's physical condition and behavior, signs and symptoms of illness, and reactions to treatment and through communication with the client and health team members; and (4) act as the client's advocate, as circumstances require, by initiating action to improve health care or to change decisions or activities which are against the interests or wishes of the client, and by giving the client the opportunity to make informed decisions about health care before it is provided. (*See* 16 C.C.R. § 1443.5.)

Because of the importance of the nurse-patient relationship, various entities have, over time, advanced proposals designed to ensure that there are sufficient numbers of nurses to meet patient needs. One such proposal has been and is minimum staffing ratios.

As early as 1992, DHS considered proposing regulations requiring staffing ratios for registered nurses in acute care hospitals. (CNA 10.) However, at that time, DHS determined not to impose minimum ratios and instead opted for regulations requiring that hospitals implement a Patient Classification System ("PCS"). (*Id.*)

The PCS was intended to ensure that the number of nursing staff was aligned to the health care needs of the patients, while still allowing the provider flexibility for the efficient use of staff. (*Id.*) The PCS regulations provide a framework to establish nursing

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staff allocations based on nursing care requirements for each shift and each unit. (22 C.C.R. § 70053.2.) The PCS system requires the establishment of a method to predict nursing care requirements of individual patients. (*Id.*) This method must address the amount of nursing care needed, by patient category and pattern of care delivery, on an annual basis, or more frequently, if warranted by the changes in patient populations, skill mix of the staff, or patient care delivery model. (*Id.*) The PCS system also requires (1) a method by which the amount of nursing care needed for each category of patient is validated for each unit and for each shift; (2) a method to discern trends and patterns of nursing care delivery by each unit, each shift, and each level of licensed and unlicensed staff; (3) a mechanism by which the accuracy of the nursing care validation method described above can be tested; (4) a method to determine staff resource allocations based on nursing care requirements for each shift and each unit; and (5) a method by which the hospital validates the reliability of the patient classification system for each unit and for each shift. (*Id.*)

Following the adoption of the PCS, DHS spent more than four years working with nursing and hospital organizations, including the CNA, to develop the final PCS regulations, which became effective on January 1, 1997. (CNA 10.)

Although it does not appear that any formal studies were conducted to determine the effectiveness of the PCS, it was the perception of some that the PCS was not meeting the patients' needs for staffing. (CNA 12 [Final Statement of Reasons for R-37-01].) CNA claims this perception was supported by a 1998 survey conducted by the DHS itself. According to the Senate Health and Human Services Committee, as reported by the Senate Rules Committee:

> "In 1998, the DHS surveyed over 160 acute care hospitals during the Consolidated Accreditation and Licensing Survey and found that most of the hospitals surveyed were not in compliance with Title 22 patient classification. 61% of the facilities were out of compliance with Title 22 with 87% deficient in the specific sections that require the facility to establish a PCS and to staff based on patient needs. . . . [I]t is clear that the majority of facilities are not complying with Title 22." (CNA 300, 1034.)

Consequently, the CNA concluded that the PCS was not meeting its intended purpose, and sponsored AB 394 to require the establishment of minimum numerical licensed nurse-to-patient ratios. (CNA 1011-12; *see also* CNA 1009 [letter to Governor from Honorable Sheila Kuehl requesting Governor to sign AB 394].)

C. Health and Safety Code Section 1276.4

AB 394 was introduced in February 1999. It immediately encountered strong opposition. The Assembly Committee on Health reported the hospital industry's opposition to legislatively mandated nurse-to-patient ratios for acute care hospitals in its April 6, 1999 report on AB 394:

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"OPPOSITION. The California Healthcare Association (CHA) opposes the bill because it legislates nurse staffing levels for hospitals based on ratios. CHA believes the public policy of the state should be to require hospitals to base nurse staffing levels on the specific care needs of the patients as measured each shift for every unit, not on staffing ratios. CHA states that hospitals across California are facing a nursing shortage and that this bill will not remedy this problem. Instead, CHA and CNA are trying to persuade the legislature to do more about increasing the number of nurses graduated. CHA states that passage of this bill will put hospitals in the position of being non-compliance [sic] because they will not be able to hire the nurses required.

"Additionally, CHA states that the ratios in this bill have no analytical basis, that staffing ratios will lead to inefficiency, and that this bill could cost hundreds of millions for hospitals with no reimbursement. Absent additional revenue, CHA states that the overall level of patient care could suffer because hospitals may decide to limit the number of patients they admit in order to accommodate the ratio requirements. If hospitals are able to find nurses to hire[,] and lay off aides and other personnel to pay for the additional nurses, then there will be service gaps." (CNA 976-83.)

Similarly, in a letter to the Governor requesting a veto of AB 394, CHA wrote:

"Ratios could have unintended consequences for patients. For example, hospital[s] may need to limit admissions in order to meet ratios, depending on the specific ratios adopted. Absent new revenue, laboratory, pharmacy, and other hospital services may have to be cut back to fund more nursing positions. These changes also will have adverse consequences." (CNA 1055.)

Other hospital organizations made similar comments. For example, the California Association of Catholic Hospitals wrote that "[a]bsent new revenue, other hospital services may have to be cut back." (CNA 1067.) The California Rehabilitation Association wrote that "[i]f hospitals are unable to comply with the ratios and are forced to close departments and units, then patient care will be jeopardized." (CNA 1069.) And Tenet Healthcare Corporation wrote that "[t]his [bill] may result in the unintended consequences of forcing hospitals to limit admissions in order to meet specific staffing ratios." (CNA 1071.)

Notwithstanding these objections from the hospital industry, in October 1999, the Legislature passed, and then Governor Gray Davis signed, AB 394, which added section 1276.4 to the Health and Safety Code. The legislative findings for the statute provide:

"SECTION 1. The Legislature finds and declares all of the following:

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(a) Health care services are becoming complex and it is increasingly difficult for patients to access integrated services.
(b) Quality of patient care is jeopardized because of staffing changes implemented in response to managed care.
(c) To ensure the adequate protection of patients in acute care settings, it is essential that qualified registered nurses and other licensed nurses be accessible and available to meet the needs of patients.
(d) The basic principles of staffing in the acute care setting should be based on the patient's care needs, the severity of condition, services needed, and the complexity surrounding those services." (Health & Safety Code § 1276.4.)

When Governor Davis signed the bill, he accompanied the measure with a "sign message" which read, in pertinent part: "Registered nurses are a critical component in guaranteeing patient safety and the highest quality health care. Over the past several years many hospitals, in response to managed care reimbursement contracts, have cut costs by reducing their licensed nursing staff. In some cases, the ratio of licensed nurses to patients has resulted in an erosion in the quality of patient care." (CNA 10.)

Based on the legislative findings, the statute expressly directs DHS to adopt, for acute care health facilities, "regulations that establish minimum, specific, and numerical licensed nurse-to-patient ratios by licensed nurse classification and by hospital unit." (Health & Safety Code § 1276.4(a).) The legislation also, and importantly, expressly provides that these ratios are to be minimums, and that the existing Patient Classification System (PCS) shall remain in place. The minimum nurse-to-patient ratios were intended to set the baseline licensed staffing requirements for each unit type without disturbing the existing PCS staffing requirements which may require supplemental staffing as circumstances warrant. Accordingly, the legislation provides that notwithstanding the minimum nurse-to-patient ratios, "[a]dditional staff shall be assigned in accordance with the documented patient classification system for determining nursing care requirements." (Health & Safety Code § 1276.4(b).)

The statute further directs that the minimum staffing ratio regulations shall be adopted "in accordance with the department's licensing and certification regulations, as stated in Sections 70053.2, 70215, and 70217 of Title 22 of the California Code of Regulations, and the professional and vocational regulations in Section 1443.5 of Title 16 of the California Code of Regulations." (Health & Safety Code § 1276.4(a).) These sections describe or explain the professional obligations of registered nurses in the provision of health care. For example, section 70053.2 describes the Patient Classification System. Section 70215 provides that an nurse must provide, among other things, ongoing patient assessments as defined in the Nursing Practice Act, and the planning, supervision, implementation, and evaluation of nursing care to each patient in accordance with the elements of the nursing process. Section 70217(j) likewise provides that nursing personnel shall assist the administrator of nursing services, provide direct patient care, and provide clinical supervision and coordination of care given by licensed vocational nurses and unlicensed nursing personnel. And, as discussed above, section

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1443.5 of Title 16 describes the applicable nursing "Standards of Competent Performance." The statute provides that "in case of conflict between this section and any provision or regulation defining the scope of nursing practice, the scope of practice provisions shall control." (Health & Safety Code § 1276.4(h).)

D. California Code of Regulation Section 70217

Prior to setting the minimum staffing ratios, DHS reviewed several proposals and received thousands of comments from interested persons and organizations, including both the CNA and the CHA. (CNA 15-21.)

CHA vigorously objected to the implementation of any minimum staffing ratios. According to the Final Statement of Reasons for R-37-01, CHA objected that there are no academic or empirical studies that define appropriate nurse-to-patient ratios in the various hospital units. CHA requested that DHS delay implementation of AB 394 until credible, evidence-based studies exist upon which to base the regulations. (CNA 19-21.)

CHA also suggested that hospitals cannot afford to hire more nurses because of the extreme fiscal constraints on hospitals caused by seismic retrofitting, Health Insurance Portability and Accountability Act (HIPPA) implementation, etc., in concert with the fiscal pressure of managed care. CHA posited that even if hospitals were able to afford to hire more nurses, there are not enough nurses available due to a nursing shortage. If hospitals cannot comply with the mandated ratios, CHA argued, hospitals will be forced to close units and suspend services, thus limiting, and possibly denying, access to care for many Californians. Closures and suspensions of service could, in turn, cause lengthy patient transports, delays in start of care, and, potentially, increased morbidity and mortality. (*Id.*)

During the rulemaking process, DHS frequently and consistently responded that concerns about fiscal issues and a possible nursing shortage were "outside the scope of the rulemaking package." DHS has listed and summarized the comments it received in respect to its proposed regulations and the DHS responses to those comments, all of which are contained in addendums to the Final Statement of Reasons for R-37-01, and were reviewed by this Court. (*See* CNA 816-958; see also DHS (compact disc) bates numbers 2938-6458, 7300-10272.) Examples of a few of DHS' responses to the comments it received are set forth below:

> "The nursing shortage is an important issue, but the proposed regulations are not, by themselves, designed to address the nursing shortage in California." (CNA 826.)
>
> "[T]he increase in hospital costs and other requirements such as earthquake retrofitting are important issues but addressing them is outside the scope of this rulemaking package." (CNA 816.)

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> "The proposed regulations are not designed to address the nursing shortage in California. The proposed regulations are the minimum licensed nurse[s] necessary to protect the health and safety of patients in general acute care hospitals in California." (CNA 823.)

In response to requests that DHS delay implementation of 1:5 ratios in Medical/Surgical units until after a study of the effects of the initial 1:6 ratios could be performed, DHS responded:

> "HSC 1276.4 mandates that the department, 'shall review these regulations five years after adoption and shall report to the Legislature regarding any proposed changes.' That is the report that the CDHS will prepare and submit. CDHS does not have the resources to conduct the study suggested by this comment." (CNA 832.)

In its Final Statement of Reasons for R-37-01, however, DHS stated that CHA's concerns about threats to access to care were relevant, along with its concern about possible nursing shortages. DHS stated that it had carefully evaluated the possibility that care and services could be diminished or denied if the proposed ratios were unreasonable. Specifically, DHS stated: "CHA's caution about imposing ratios that will place heavy and unnecessary burdens on the fiscal reserves of providers deserved and received thoughtful and deliberate consideration." (CNA 20-21.) In the end, DHS reached the following conclusion:

> "[G]iven the statutory mandate, CDHS did not have the option of declining to implement the ratios, notwithstanding the nursing shortage and the hospitals' financial concerns. However, the Department did evaluate a multitude of factors effecting acute care, and is working toward facilitating compliance with the staffing ratios while easing any undue fiscal burdens by providing maximum flexibility for hospitals within the bounds of patient health and safety. CDHS also chose to phase-in the richer ratios for Medical/Surgical units for one year, and for Step-down, Telemetry, and Specialty Care units for four years in order to allow providers time to develop a strategy for compliance, for the recruitment of additional nurses, and for the education and training of additional classes of nursing students." (*Id.* [emphasis added])

In response to concerns raised about California's nursing shortage, DHS noted that then-Governor Davis had just announced his Nurse Workforce Initiative, a $60 million effort to address the nursing shortage in California. (*Id.*)

Although CHA objected to the implementation of ratios in general, CHA nevertheless proposed specific minimum ratios for each unit, including a proposed 1:10 ratio for Medical/Surgical Units. CNA, in turn, proposed its own specific minimum ratios, which generally were higher than those proposed by CHA, including a proposed 1:3 ratio for Medical/Surgical Units. (CNA 16, 20-21.) In its Final Statement of

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Reasons, DHS found that neither CNA's nor CHA's proposal presented an adequately supported basis for the specific proposed ratios. Therefore, DHS attempted to reach a "broader, more objective" consensus of reasonable standards that would improve nurse staffing levels and quality of care to patients. (CNA 21.)

In addition to soliciting the perspectives of major stakeholders, DHS reportedly performed an extensive review of existing literature, solicited recommendations of professional medical organizations, held discussions with other states and countries about their experiences with acute care staffing, and extracted information about nurse staffing from Office of Statewide Health Planning and Development (OSHPD) data. DHS also solicited input from professional nurses on its own staff. However, because none of the sources of information provided DHS with hard scientific evidence of the optimal nurse staffing ratio for each individual unit, DHS also conducted an on-site hospital study to discover the level of nurse staffing practiced in hospitals in the absence of the proposed ratio regulations. According to DHS, the study also gave DHS the opportunity to estimate the FTE [full time equivalents] and fiscal deficits that may occur with various ratio proposals, and provided a foundation for the required study evaluating the effect of these regulations five years after adoption. (CNA 28.)

With this background, DHS adopted the ratios set forth in DHS Regulation R-37-01. The ratios were described as "represent[ing] the leanest staffing the Department believes [are] compatible with safe and quality patient care in the acute care setting." (CNA 30 [emphasis added].)

According to the Final Statement of Reasons, the ratios represent the maximum number of patients that can be assigned to any one nurse at any one time. Because of flexible shift scheduling in hospitals, DHS believed it was not feasible to reduce nursing staff during evening, night, or weekend hours. Therefore, the ratios represent the minimum staffing permitted on any shift.

It was DHS' express intent not to permit averaging the numbers of patients and nurses during a single shift, nor averaging over time. DHS stated its belief that averaging over time would not conform to the Legislature's intent, nor the Governor's message when he signed the bill into law; nor would it provide the needed safeguard for patients in California's acute care hospitals to be cared for by adequate numbers of nursing staff. (CNA 31.)

Among the minimum ratios it established for specific units of hospitals was a 1:4 ratio for Emergency Departments ("EDs"). At the time, DHS stated that the methodology for determining appropriate nurse-to-patient ratios in EDs is problematic for several reasons, including the great variation in patient acuity and visit frequency that an individual ED can experience over a 24 hour period. In addition, EDs can be severely impacted by trauma and critical care admissions. DHS concluded that these idiosyncratic staffing patterns necessitated creating a multifaceted regulation for nurse-to-patient ratios in EDs. (CNA 38-39.)

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The nurse-to-patient ratio in medical, surgical, and combined medical/surgical units was proposed to be 1:6 or fewer at all times. DHS stated that there is "no independent, empirical information about appropriate staffing levels in medical, surgical, and combined medical/surgical units." Therefore, in determining the appropriate ratio, DHS relied heavily on Office of Statewide Health Planning and Development (OSHPD) data showing that 75% of California's hospital shifts already are staffed at a level of 1:5.6 or higher for medical/surgical units, and DHS' on-site study of hospitals statewide confirmed staffing in those unit types at 1:6 for 75% of all medical/surgical and mixed unit shifts. DHS decided to set the "starting point" for the minimum ratios at this level to improve staffing on those shifts in the leanest 25th percentile. The same study showed that at the time of the study approximately 50 percent of all hospitals were meeting the 1:5 ratio in their medical/surgical units. Therefore, DHS determined that, commencing January 1, 2005, the nurse-to-patient ratio in medical, surgical and combined medical/surgical units would be lowered to 1:5 or fewer at all times. "CDHS has decided to increase staffing on these unit shifts incrementally, by a later phase-in of this lower ratio. This is being done for both practical and clinical reasons." (CNA 43-45.)

In a practical sense, DHS stated that because medical, surgical, and combined medical/surgical units are the most common and largest unit types in acute care hospitals, and because of the current nursing shortage, an incremental phase-in of a lower ratio is warranted to allow providers additional time to build up their pool of nurse staffing resources and adequate lead time to develop a budget strategy for complying with the minimum standards before they are mandated. It also puts providers, along with the Medi-Cal program, on notice so that they can make any needed adjustments. (CNA 44-45.)

In a clinical sense, DHS stated that because medical/surgical units are the settings where the majority of acute care patients receive care, DHS found it "important to enrich staffing" in those units. "Increasing staffing in this unit will increase the nursing care received by the greatest number of patients." Accordingly, even though DHS found that the minimum staffing level at medical/surgical units should be 1:5, in order to allow providers time to develop a strategy for compliance, for the recruitment of additional nurses, and for the education and training of additional classes of nursing students, DHS agreed to allow the minimum ratio to be "phased in" over the course of one year. Thus, the initial minimum staffing ratio was set at 1:6, with the 1:5 ratio scheduled to take effect on January 1, 2005. (*Id.*)

DHS also added a subsection to require additional recordkeeping that would ensure that specific nursing personnel could be linked to specific patients. According to DHS, this was necessary because without such a provision "it would be impossible for CDHS or the public to know retrospectively whether the facility complied with these proposed regulations and would therefore make enforcement of these proposed regulations virtually impossible." Without such a recordkeeping requirement, agents of the state department would only know in the aggregate the numbers of patients and nurses on each shift, and could calculate the average staffing, but would be unable to

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assess whether a violation occurred, or prevent a violation of these proposed regulations which implement and make specific HSC 1276.4." (CNA 40-49.)

In addition, DHS added a subsection providing that if a "healthcare emergency" causes a change in the number of patients on any unit, the hospital will not violate the regulations so long as the hospital demonstrates that prompt efforts were made to maintain the required staffing levels. A "healthcare emergency" was defined as an "unpredictable or unavoidable occurrence at unscheduled or unpredictable intervals relating to healthcare delivery requiring immediate medical interventions and care." (February 17, 2005, Declaration of Gina Henning, Exh. D, p. 11.) This subsection reflected DHS' intent to give the hospital needed flexibility while the hospital makes prompt, diligent efforts to return each unit to the minimum required staffing ratios. (CNA 49-50.)

The DHS regulation was adopted on August 26, 2003, and filed with the Secretary of State on September 26, 2003, with an effective date of October 26, 2003. By the regulation's terms, the staffing ratios became operational on January 1, 2004.

E. Emergency Regulation R-01-04E

In November 2003, Governor Davis was recalled and succeeded by Governor Schwarzenegger. Approximately one year later, on or about November 4, 2004, DHS gave notice that it had adopted the initial Emergency Regulation (R-01-04E).

The Initial Statement of Reasons for the Emergency Regulation provides that hospitals claim they are unable to hire enough nurses for continuous compliance with the regulations because of California's nursing shortage. It also states that hospitals have reported that they do not have sufficient funds to hire enough nurses because of a number of factors, including the pressures of managed care, inadequate Medi-Cal reimbursement rates, an ever-increasing uninsured population receiving their health care through emergency departments, unfunded mandates (including seismic retrofit), as well as the nurse-to-patient staffing ratios. DHS stated that it carefully considered these concerns and decided that some modifications to the original regulations were necessary. (February 17, 2005, Declaration of Barbara Gallaway, Exh. A, Initial Statement of Reasons for R-01-04E; *see also* CNA 337-45.)

The Emergency Regulation that took effect postpones until January 1, 2008, the step-down of the ratio for medical, surgical, medical/surgical, and mixed units from 1:6 to 1:5 that was set to take effect on January 1, 2005. In addition, the Emergency Regulation amends DHS' staffing regulation to (i) clarify when licensed nurses shall be counted towards the ratios; (ii) change the recordkeeping requirements for emergency departments so that emergency departments will no longer be required to track nurse assignments to specific patients in those units; and (iii) allow emergency departments to deviate from staffing ratios in the event of "saturation" instead of only when there is a "healthcare emergency." (*Id.*)

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In accordance with Government Code section 11346.1(b), DHS made a Finding of Emergency, in which it found that the Emergency Regulation is "necessary for the immediate preservation of the public health and safety." (February 17, 2005, Declaration of Barbara Gallaway, Exh. A, Finding of Emergency for R-01-04E; *see also* CNA 2-7.) DHS stated that it is "vital to the health and safety of all Californians that the state maintains a health care delivery system that includes adequate facilities and staff to meet patient needs." (*Id.*) DHS found that "[d]uring the ten months that nurse-to-patient ratios have been in effect, they have been cited as a cause for closure of two hospitals and the closure or reduction in capacity of several hospital emergency rooms and other patient care units." (*Id.*) In addition, DHS stated that it had become aware of "reports of hospitals reducing the availability of services." (*Id.*)

Significantly, DHS also indicated that:

> "[It] does not have data to support or refute these and other claims that have been made about problems caused or exacerbated by the current nurse-to-patient ratios. However, the maintenance of hospitals and hospital services is vital for the safety and health of all Californians. Therefore, the Department has a responsibility to recognize early indications of unanticipated consequences on a health care system already reported to be under stress. While nurse-to-patient ratios are an important component of patient care in California, they are not the only component. . . . [Until the Department can complete the statutorily required study of current ratios,] it is inappropriate to risk unintended consequences of enriched nurse-to-patient ratios on the availability of hospital services in California." (*Id.* [emphasis added])

In respect to the clarification of when licensed nurses should be counted towards the ratios, DHS indicated that "it is critical that the Department clarify the application of the nurse-to-patient ratios that are currently in effect," because interpretations of the current regulations may have "unduly restricted the eligibility of nurses to be counted for patient assignment." (*Id.*)

Finally, DHS indicated that "the unique character of hospital emergency departments makes it necessary to adjust terminology and the method of recording nurse assignments to patients." According to DHS, the amendments would "make the application of the ratios more congruent with the reality of emergency department staffing and allow hospitals needed flexibility in emergency departments." (*Id.*)

On or about December 21, 2004, Petitioner CNA filed this action challenging the Emergency Regulation.

On March 3, 2005, the Court tentatively ruled that the November 12 Emergency Regulation would be enjoined. That same day, DHS adopted the second Emergency Regulation, which was identical in content and format to the original Emergency Regulation, which was set to expire by operation of law on March 14, 2005. On March

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14, 2005, this Court issued its final orders preliminarily enjoining both the November 12 and March 3 Emergency Regulations pending final disposition of the Petition.

III.
Discussion

As described above, CNA challenges the Emergency Regulations on the following grounds. First, CNA argues that the Emergency Regulations are invalid because they (i) exceed the scope of authority conferred to DHS by the Legislature; (ii) are not reasonably necessary to effectuate the purposes of the statute; and (iii) would, if permitted to stand, result in a violation of the constitutional principle referred to as separation of powers. Second, CNA argues that the Emergency Regulations are invalid because the decision to adopt an "emergency" regulation is not supported by the findings, and the findings are not supported by the evidence.

CNA's challenges require the Court to determine whether DHS properly interpreted its legislative mandate in promulgating the Emergency Regulation. In reviewing the validity of a regulation adopted pursuant to a delegation of legislative power, the judicial function is to determine whether the regulation is (1) within the scope of the authority conferred by the statute, and (2) reasonably necessary to effectuate the purposes of the statute. (*Ralphs Grocery Co. v. Reimel* (1968) 69 Cal.2d 172, 175.)

A. *Does the Emergency Regulation Exceed The Scope Of Authority Conferred On DHS By The Legislature?*

In general, the court's task is to inquire into the legality of the challenged regulation, not its wisdom. (*Mahdavi v. Fair Employment Practice Com.* (1977) 67 Cal.App.3d 326, 338.) When an administrative agency is charged with enforcing a particular statute, its interpretation of the statute generally will be accorded deference by the courts. (*C.E. Buggy, Inc. v. Occupational Safety & Health Appeals Board* (1989) 213 Cal.App.3d 1150, 1156.)

However, in *Yamaha Corp. v. State Bd. of Equalization*, the Supreme Court distinguished an agency's quasi-legislative rules, which are accorded great deference, from an agency's legal interpretations of a controlling statute, which are entitled to a "lesser degree" of judicial deference "appropriate to the circumstances." (*Yamaha Corp. v. State Bd. of Equalization* (1998) 19 Cal.4th 1, 8, 12.) Moreover, deference principles do not allow an agency to disregard a statute's plain language. An interpretation that enlarges or exceeds the scope of authority delegated to the agency or that rejects explicit legislative policy determinations cannot be sustained. (Govt. Code § 11342.1; *People ex rel. Dept. of Alcoholic Beverage Control v. Miller Brewing Co.* (2002) 104 Cal.App.4th 1189, 1198-99.) Because the interpretation of the statute is a question of law, case law is clear that the Court, not the agency, is the ultimate arbiter of the interpretation of the law under which the regulation was issued. (*Yamaha Corp.*, *supra*, at p. 11 fn.4.)

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In this case, CNA argues that the Emergency Regulation exceeds the scope of lawful authority conferred on the DHS by the Legislature because AB 394 does not allow for decisions which accommodate perceived nursing shortages or conflicting economic interests. If CNA's interpretation is correct, then CNA must prevail because the very basis for the Emergency Regulation was to account for "reports" that hospitals are being forced to close or reduce services because of a nursing shortage and a lack of sufficient funds.

In ascertaining the intent of a statute, the Court is guided by well-established rules of statutory interpretation. In construing a statute, a court must look first to the language of the statute itself. If possible, significance should be given to every word, phrase, sentence and part of an act in pursuance of the legislative purpose. (*Phelps v. Stostad* (1997) 16 Cal.4th 23, 32.) If there is no ambiguity in the language of the statute, then the Legislature is presumed to have meant what it said, and the plain meaning of the language governs. "When the language is clear and there is no uncertainty as to the legislative intent, we look no further and simply enforce the statute according to its terms." (*Id.*)

Here, the language of the statute is unambiguous. The statute provides that DHS "shall adopt regulations that establish minimum, specific, and numerical licensed nurse-to-patient ratios" for all specified health facilities. (Health & Safety Code § 1276.4(a).) In directing DHS to determine the minimum staffing ratios, the legislative findings for the statute make clear that the purpose of the ratios is to safeguard the health, safety and well-being of patients in acute care settings. The legislative findings declare that the "[t]he basic principles of staffing in the acute care setting should be based on the patient's care needs, the severity of condition, services needed, and the complexity surrounding those services." (Health & Safety Code § 1276.4, Legislative Findings, Section 1(d).) The Legislature declared that the "[q]uality of patient care is jeopardized because of staffing changes implemented in response to managed care." (Health & Safety Code § 1276.4, Legislative Findings, Section 1(b).) Because of these concerns about the effect of "staffing changes" on quality of care, the Legislature found it "essential" that nurses be "accessible and available" to meet the needs of patients "in acute care settings." (Health & Safety Code § 1276.4, Legislative Findings, Section 1(c).)

The Legislature's concerns about the quality of hospital care is further reflected in the text of the statute itself. For example, the statute authorizes DHS to grant rural hospitals waivers of the minimum staffing ratios needed for "increased operational efficiency," but only upon a finding that such waivers will "not jeopardize the health, safety, and well-being of patients affected . . . ." (Health & Safety Code § 1276.4(g) [emphasis added].) Similarly, DHS is authorized to consider the unique nature of the University of California teaching hospitals when establishing the minimum ratios, "provided there will be sufficient direct care registered nurse preceptors available to ensure safe patient care." (Health & Safety Code § 1276.4(l) [emphasis added].) In establishing the ratios, DHS is required to consider the professional and vocational regulations of nurses that establish "competent" patient care, (Health & Safety Code § 1276.4(a) [referring to 22 CCR § 70215; 22 CCR § 70217; 16 CCR § 1443.5; and 22

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CCR § 70053.2]), and the statute prohibits nurses from being assigned to a unit unless that nurse has received orientation and demonstrated the ability "to provide competent care" to patients in that area. (Health & Safety Code § 1276.4(e) [emphasis added].)

With limited exceptions, there is no mention in the statute about concerns for the the number of hospitals that may be made available, or any expression of an intent to ensure the accessibility and availability of acute care services in all circumstances. An exception is subsection (g), discussed above, which authorizes DHS to grant waivers for the minimum staffing ratios "needed for increased operational efficiency," provided such waivers "do not jeopardize the health, safety, and well-being of patients." By implication, this shows that concerns of "operational efficiency" were intended to be subordinate to the health and safety of the patients. This language also shows that the Legislature knows how to expressly require agencies to consider operational efficiencies or other considerations when it wants to. (*See* Health & Safety Code § 1276.4(g), (k), (l) [authorizing special consideration for rural hospitals, mental health facilities, and University of California teaching hospitals]; *see also, e.g.*, Water Code § 13241 [setting forth factors, including industry economics, which are to be considered by agency in establishing regulations and objectives].) The absence of such a requirement here suggests that the Legislature did not intend to grant general acute care hospitals the authority to determine the ratios based on such considerations.

For all of these reasons, the Court finds that the statutory language unambiguously establishes that the purpose of the proposed minimum staffing ratios is to enhance the *quality* of care, i.e., to protect the health and safety of patients in acute care hospitals in California. Therefore, considerations of nursing shortages and economic impacts appropriately are outside the scope of DHS' rulemaking authority.

Respondent DHS takes issue with the Court's authority to interpret the statute, and contends that the DHS' view of the statute should be entitled to "great weight unless clearly erroneous or unauthorized." (DHS Opposition, at p. 19.) However, the California Supreme Court rejected this view in *Yamaha*:

> "Quasi-legislative rules are reviewed independently for consistency with controlling law. A court does not, in other words, defer to an agency's view when deciding whether a regulation lies within the scope of the authority delegated by the Legislature. The court, not the agency, has 'final responsibility for the interpretation of the law' under which the regulation was issued." (*Yamaha*, *supra*, at p. 11 fn. 4; *see also* Govt. Code § 11342.1 [stating no regulation adopted is valid or effective unless consistent with and not in conflict with the enabling statute].)

Moreover, even if the DHS' interpretation of the statute were entitled to great deference, the administrative record establishes that DHS' interpretation of the statute has not been consistent. In many instances, DHS' interpretation of the statute was entirely in accord with the Court's interpretation. For example, DHS commented about AB 394 before it was signed that "[t]he intent of the bill is to maintain quality patient care by

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prohibiting unlicensed personnel from performing nursing functions and through nurse-to-patient ratios." (CNA 1014.)

Additionally, in response to public comments about the proposed staffing ratios, DHS consistently declined to modify or delay the proposed ratios based on concerns about the perceived nursing shortage in California. According to DHS, "[t]he proposed regulations are not designed to address the nursing shortage in California." (CNA 879, 881, 885, 914, 924-25, 927-33, 935-49, 953, 955-56; *see also* CNA 877, 923, 952 ["The proposed regulations are not, by themselves, designed to address the nursing shortage in California. That is outside the scope of these regulations."]; CNA 926, 954 [same]; CNA 878, 904, 934 ["Addressing the nursing shortage is outside the scope of this rulemaking package"]; CNA 892 ["[t]he lack of available nurses and use of registry and travelers are important issues but addressing them is outside the scope of this rulemaking package."]; CNA 894 ["While the nursing shortage is an important issue, addressing it is outside the scope of this rulemaking package"]; CNA 924 [same]; CNA 950 ["The lack of available, competent, trained, and knowledgeable registered nurse[s] in all areas of the state is an important issue, but it is not addressed within the scope of the regulatory package."].)

DHS similarly rejected comments that compliance with the ratios would cause hospitals to close or deny access, responding that such concerns also were "outside the scope of the rulemaking package." (CNA 881 ["Addressing the cost of resolving the acute care nursing deficit statewide is outside the scope of this rulemaking package"]; CNA 887, 903 [finding concerns that ratios too costly and endanger ability to serve communities to be outside scope of rulemaking package]; CNA 888 [finding regulations' estimated $486 million price tag to be outside scope of rulemaking package]; CNA 894, 909-10 ["Addressing the business and fiscal constraints faced by hospitals is outside the scope of this rulemaking package"]; CNA 895-96, 904 ["Addressing the fiscal constraints faced by hospitals is outside the scope of this rulemaking package"]; CNA 900 [The increase [sic] hospital costs are important issues but addressing it is outside the scope of this rulemaking package"]; CNA 915 ["the fiscal constraints facing hospitals is an important issue, but addressing it is outside the scope of this rulemaking proceeding"]; CNA 923 ["Although hospital costs is an important issue, addressing them is outside the scope of the rulemaking proceeding"]; CNA 951 ["Although the increased hospital costs, the education and availability of nurses, are all important issues, they are outside the scope of the rulemaking package"].)

Instead, DHS consistently took the position that "the proposed ratio regulations are the minimum licensed nurses necessary to protect the health and safety of patients in general acute care hospitals in California." (CNA 879, 881, 885, 914, 924-25, 927-33, 935-49, 953, 955-56; see also CNA 876, 878 [same]; CNA 877 ["[t]he proposed ratios represent the minimum number of nurses that can safely provide care to patients on the various units of general acute care hospitals"]; CNA 879 [same]; CNA 881-85, 887-88, 893, 895-96, 898, 903-05, 951 ["[t]he proposed ratios for each unit are the minimum numbers of licensed nurses necessary to protect the health and safety of patients in California's acute care hospitals."]; CNA 915 [same]; CNA 920 ["[i]t was the provision of the quality of patient care and the adequate protection of patients in the acute care

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setting that was the basis of these proposed regulations for nurse to patient ratios"]; CNA 874, 885, 890-91, 921, 934, 942, 949, 952, 955-57 ["[t]hese ratios are mandated to be the minimum level to protect the health and safety"].)

DHS reiterated this interpretation in its Initial and Final Statements of Reasons for the original Regulation, stating that the proposed ratios constituted the "minimum necessary to protect the public health and safety." (CNA 10, 458; see also CNA 30-31, 478.) As stated by DHS itself: "The Legislature clearly believed that the quality of patient care was related to the number of licensed nurses at the bedside, and wished to ensure a minimum, adequate number." (CNA 10, 458 [emphasis added]; *see also* CNA 30-31, 478.) Therefore, DHS adopted ratios setting forth what it described as "the leanest staffing the Department believes is compatible with safe and quality patient care in the acute care setting." (CNA 30.)

In sum, throughout the public comment period for the initial rulemaking proceeding, DHS stated that hospital finances and the lack of available nurses are matters outside the scope of the rulemaking package. Notwithstanding these comments, DHS plainly was concerned about such issues. Before AB 394 was signed into law, DHS had recommended that it be vetoed based, in part, on concerns that the costs of care in facilities may increase due to the ratios and that hospitals may not be able to meet the ratios due to nursing shortages and the lack of a phase-in period. (CNA 1016 [emphasis added].) Although DHS stated that it was not opposed to the concept of nurse-to-patient ratios because it "supports the appropriate use of nursing staff at levels necessary for good patient care," DHS stated that the provisions of "AB 394 present technical obstacles that are unrealistic and/or unnecessary," such as "an unrealistic timeline" for the Department to develop and implement nurse staffing ratios. (CNA 1014-15.) DHS recommended that all hospitals be given "a phase-in period" to comply with the minimum, safe ratios. (CNA 1016.)

The record establishes that prior to the adoption of the initial non-emergency regulation, DHS gave careful attention to the CHA's concerns that care and services could be diminished or denied by the proposed staffing ratio regulation:

> "CHA's essential premises include the observation that there are currently no academic or empirical studies that define nurse-to-patient ratios that are appropriate for improving the quality of patient care in the various hospital units. CHA suggested, therefore, that CDHS delay implementation of AB 394 until there are credible, evidence-based studies upon which to base the regulations. CHA also suggested in other communications with CDHS that nurse-to-patient ratios may negatively impact the quality of care if they cause the utilization of higher percentages of nurses at the expense of a 'milieu rich in clinical diversity.' They argued, on behalf of their membership, that hospitals cannot afford to hire more nurses because of extreme fiscal constraints caused by seismic retrofitting, Health Insurance Portability Accounting Act (HIPPA) implementation, etc., in concert with the fiscal pressure of managed care. They further posited that, even if

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hospitals somehow were able to afford to hire more nurses, there aren't enough nurses available due to the nursing shortage. They stated that, if hospitals cannot comply with the mandated ratios, hospitals will be forced to close units and suspend services, thus limiting, and possibly denying, access to care for many Californians. Closures and suspensions could, in turn, cause lengthy patient transports, delays in start of care, and, potentially, increased morbidity and mortality."

"CHA's . . . concerns about limiting access to care are especially relevant, and CDHS has carefully evaluated the possibility that care and services could be diminished or denied if the proposed ratios were unreasonable. CHA's caution about imposing ratios that will place heavy and unnecessary burdens on the fiscal reserves of providers deserved and received thoughtful and deliberate consideration."

"However, given the statutory mandate, CDHS did not have the option of declining to implement the ratios, notwithstanding the nursing shortage and the hospitals' financial concerns. However, the Department did evaluate the multitude of factors effecting acute care, and is working toward facilitating compliance with the staffing ratios while easing any undue fiscal burdens by providing maximum flexibility for hospitals within the bounds of patient health and safety." (CNA 20-21.)

Ultimately, DHS established the minimum nurse to patient ratio, but allowed for an incremental phase-in of the staffing ratios for Medical/Surgical units, over one year, purportedly to allow providers time to develop a strategy for compliance, plan their budgets, and build up their pool of nurses before the lower staffing ratios were mandated. (CNA 20-21, 44-45.) Although DHS proposed to phase-in implementation of the ratios for certain units, DHS steadfastly rejected all pleas from the public that it delay implementing any of the ratios beyond what was proposed by DHS: "CDHS believes these proposed ratios represent the minimum level of nurse staffing required to protect the health and safety of patients in California's acute care hospitals. Because of the lengthy rulemaking process mandated by the Administrative Procedures Act, and because of the volume of comments which have had to be reviewed, logged, and responded to, the regulations have already been delayed from their mandated implementation date of 01/01/03. CDHS declines to further delay implementation of the proposed regulations." (CNA 909; *see also* CNA 881-82, 887-88, 891, 895-96, 903-04.)

The Court notes that in doing so, DHS flatly contradicted its prior statements that the nursing shortage and hospital economic impacts were outside the scope of the rulemaking package. The original one-year delay of the 1:5 ratio was not challenged and is not at issue here. To the extent DHS argues that the original one-year delay of the 1:5 ratio establishes that it has the authority to delay implementation of the staffing ratios, the Court rejects this argument as unfounded. (*See also* further discussion in this section, *infra*, regarding a related argument on enrichments.) The Court's interpretation is that

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considerations of nursing shortages and economic impacts are outside the scope of DHS' rulemaking authority.

As explained above, the Court's interpretation is based on the plain language of the statute, but the Court's interpretation also is consistent with the legislative history of the statute. As described in the April 6, 1999, report of the Assembly Committee on Health, the purpose of AB 394, as described by its sponsor (CNA) was to establish specific nurse-to-patient ratios, such as those already established for ICUs and other medical units in health care facilities. (CNA 979.) According to the CNA, RNs are a critical component in guaranteeing patient safety and the highest quality care. (CNA 978.) CNA claimed that over time, in response to managed care, hospitals had cut costs by reducing their licensed nursing staff – in some cases requiring nurses to perform at unprofessional levels of care. (CNA 978.) CNA also claimed that numerous studies documented a clear and direct relationship between low skill mix and increased infections, higher mortality rates, increased illness and errors. (CNA 978.) CNA claimed that even though hospitals were enjoying record profits, hospitals still lacked adequate nursing staff. (CNA 978.) Supporters of the bill stated that the results of inadequate staffing can be horrendous, and that AB 394 was necessary to ensure safe care for California patients. (CNA 978-79.)

The report indicates that opponents of the bill argued that passage of the bill would put hospitals in the position of being noncompliant because they will not be able to hire the nurses required. Opponents also argued that the overall level of patient care could suffer because hospitals may decide to limit the number of patients they admit to accommodate the ratios. (CNA 980.)

In sum, Assembly Committee the report shows that AB 394 was intended to remedy perceived inadequacies of nursing ratios in hospitals, and that it always was understood that AB 394 could result in substantial increased costs to the health care system and that hospitals ultimately might limit or deny services to comply with the ratios. (*See also* CNA 1009 [declaring that hospitals do not currently staff at safe ratios]; CNA 1027 [reporting that to the extent the bill increases hospital staffing, it will result in substantial increased costs to the health care system]; CNA 1035 [reporting that sponsors of bill allege patient care is suffering due to a lack of registered nurses in hospitals]; CNA 1077-78, 1084 [claiming that AB 394 could lead to unintended consequences for patients as hospitals may need to limit patient admissions to meet ratios]; CNA 1055 [letter from CHA indicating that proponents of AB 394 have done an excellent job of convincing the Legislature that the quality of patient care in California hospitals is dangerously low due to short staffing of nurses].) The Court's interpretation is also consistent with this position.

The Court's interpretation also harmonizes the language of the statute in the context of the broader statutory scheme of which it is a part. (*Phelps v. Stostad* (1997) 16 Cal.4th 23, 32 [finding the various parts of a statutory enactment must be harmonized by considering the particular clause or section in the context of the statutory framework as a whole]; *see also People v. Jenkins* (1995) 10 Cal.4th 234, 246 [court must select the

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construction that comports most closely with the apparent intent of the Legislature, with a view to promoting rather than defeating the general purpose of the statute].)

AB 394 was adopted against the background of the "patient classification system" (PCS), which was designed to determine nursing care levels based on individual patient care requirements. (22 C.C.R. § 70053.2.) The PCS was intended to assure that the amount of nursing staff would be aligned to the health care needs of the patients, while allowing providers maximum flexibility for the efficient use of staff. (CNA 10.) In opposition to AB 394, CHA argued that AB 394 was unnecessary because the PCS already was in place to assure that hospitals will have safe and appropriate levels of nursing staff. (CNA 1055.)

However, it was the perception of CNA and others that the PCS was not accurately reflecting the patients' needs for increased staffing. (CNA 12 [HSC 1276.4 "adds a needed refinement to the existing PCS requirement"]; *see also* CNA 1034 [referring to Senate Health and Human Services Committee analysis finding that "it is clear that the majority of facilities are not complying with Title 22 [patient classification]."]; CNA 1009 [indicating that hospitals "do not currently staff at safe ratios and do not follow the current cumbersome and unworkable regulations"].) "Consequently, the Legislature passed, and the Governor signed, AB 394 requiring the establishment of minimum numerical licensed nurse-to-patient ratios." (CNA 12 [Final Statement of Reasons for R-37-01] [citations omitted].)

The minimum staffing ratios were intended to co-exist with, not to supplant, the PCS requirements. (CNA 12.) As stated by DHS: "HSC 1276.4 adds a needed refinement to the existing PCS requirements. The establishment of minimum nurse-to-patient ratios will set the baseline licensed staffing requirement for every unit type. . . . The PCS will remain in place to indicate the needed increases beyond minimum licensed staffing as patient acuity increases." (CNA 12.) This undermines any notion that the minimum staffing ratios could encompass discretionary enrichments. The statutory scheme plainly contemplates that the minimum staffing ratios are intended to set the baseline staffing requirements, and that the PCS would effect any enrichments. DHS itself has affirmed this interpretation: "The Patient Classification System (PCS), already required in current regulation, will remain in place to enrich staffing above the minimum in response to patient acuity and patient care needs." (CNA 956-57 [emphasis added]; *see also* CNA 908, 951.)

Therefore, when the minimum staffing ratios are considered in context, it is clear that the purpose of the minimum staffing ratios was to remedy the perceived failure of the PCS to assure that hospitals provide safe and appropriate levels of nursing staff to their patients. Accordingly, considerations of nursing shortages and economic impacts are not appropriately within the scope of DHS' rulemaking authority on minimum nurse to patient safe ratios.

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Finally, even though the Court reaches its interpretation of the statute independently, the Court finds additional support for its interpretation in the Legislature's rejection of Assembly Bill No. 2963 (Pacheco) during the 2003-04 term. (*See* CNA 234-235, 242 [April 20, 2004, report of Assembly Committee on Health on AB 2963].) AB 2963, which was sponsored by CHA, would have prohibited DHS from implementing the 1:5 ratio in medical/surgical units until DHS is able to demonstrate that all of the following conditions are satisfied: (1) there is a sufficient supply of nurses available to meet a 1:5 nurse-to-patient ratio requirement with no loss of bed availability; (2) there are measurable improvements to patient care as a result of a 1:5 nurse-to-patient ratio requirement; and (3) the cost projected in moving from a 1:6 nurse-to-patient ratio to a 1:5 nurse-to-patient ratio does not exceed projected revenues. (*Id.*) The Assembly Committee report states that CHA sponsored the bill because CHA believed that it is not desirable or logical to implement the 1:5 ratio prior to knowing the effect of the implementation of the 1:6 ratio. (*Id.*) CHA asserted that criteria to determine if the 1:5 ratio should be implemented must include the availability of nurses and demonstrate measurable improvement in in-patient care, including whether or not the improvement justifies the additional cost. (*Id.*) By seeking to obtain legislative amendment of the existing statute, CHA arguably implicitly admitted that legislative authorization was needed for such criteria to be considered by DHS. (*See American Ins. Assn. v. Garamendi* (2005) 2005 Cal. App. LEXIS 301, *35-36.)

Furthermore, although it is difficult to determine the precise meaning of the Assembly Committee's rejection of the proposed amendment, the Court does not ignore that the Legislature's decision not to adopt the proposed amendment is in accord with this Court's interpretation that the Legislature does not intend for DHS to consider such factors in its rulemaking.

The Court sees the logic of Respondent's position that nurses will not be "accessible and available" to care for patients if the hospital at which they are working is closed or reduces its services. However, drafting statutes to conform with policy considerations is a job for the Legislature, not the courts. (*California Ins. Guarantee Assn. v. Workers' Comp. Appeals Bd.* (2005) 128 Cal.App.4th 307, 316.) When interpreting statutes, courts are bound to adhere to the Legislature's intent, as evinced by the plain meaning of the actual words of the law. (*Gillespie v. San Francisco Pub. Library Com.* (1998) 67 Cal.App.4th 1165, 1174.) In this case, the express language of the statute makes clear that the legislation was intended to protect a specific segment of the general population, namely, "patients," and more specifically, "patients in acute care settings."[1] (Health & Safety Code § 1276.4, Legislative Findings, Section 1(c); *see also* CNA 30 [The ratios represent "the leanest staffing the Department believes is compatible with safe and quality patient care in the acute care setting" (emphasis added)], CNA 30-31 [ratios must "provide the needed safeguard for patients in California's acute care hospitals"].) The Court cannot simply ignore this language in interpreting the meaning of the statute.

[1] The statutory language at issue here must be distinguished from the "broad and flexible" statutory directive discussed in *Pulaski v. California Occupational Safety and Health Standards Board* (1999) 75 Cal.App.4th 1315, 1334.

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Accordingly, it is the Court's interpretation that considerations of nursing shortages and economic impacts are outside the scope of the rulemaking because such considerations are inconsistent with the fundamental purposes of the statute to ensure that nurses be accessible and available to meet the needs of "patients in acute care settings." Respondent DHS was under a non-discretionary statutory mandate to adopt nurse-to-patient staffing ratios without consideration of nurse availability or economic impacts to the hospitals.

The stated grounds for DHS' decision to enact the Emergency Regulation are fundamentally inconsistent with the purposes of the statute. The express intent of the Emergency Regulation is to address reports of hospitals closing or reducing the availability of services due to financial strains caused by the ratios or difficulty in finding an adequate number of nurses to comply with the ratios. (CNA 2.) DHS found that "[w]hile nurse-to-patient ratios are an important component of patient care in California, they are not the only component." (CNA 3.) "It is vital to the health and safety of all Californians that the state maintains a health care delivery system that includes adequate facilities and staff to meet patient needs." (CNA 2.) Therefore, until DHS can complete a study to determine the patient, workforce and institutional effects of the current ratios, DHS determined that it is "inappropriate to risk unintended consequences of enriched nurse-to-patient ratios on the availability of hospital services in California." (CNA 3; *see also* CNA 339 ["[T]he Department must weigh the ratios against any unanticipated consequences that ratios may have on the health care system"]; CNA 3 [the Department "has a responsibility to recognize early indications of unanticipated consequences on a health care system already reported to be under stress"].) Accordingly, DHS concluded that amending the current nurse-to-patient ratio regulations to postpone what it called the "enrichment" of the ratios that would begin on January 1, 2005, until January 1, 2008, was necessary for the immediate preservation of public health and safety. (CNA 4.) This was error.

The Legislature made fundamental policy decisions that quality of patient care is jeopardized because of staffing changes implemented in response to managed care; that to ensure the adequate protection of patients in acute care settings, it is essential that qualified registered nurses and other licensed nurses be accessible and available to meet the needs of patients; and that staffing in the acute care setting should be based on the patient's care needs, the severity of condition, services needed, and the complexity surrounding those services. The Legislature implemented this policy through an explicit statutory mandate directing DHS to adopt regulations establishing minimum, specific, and numerical nurse-to-patient ratios by licensed nurse classification and by hospital unit for all acute care hospitals. Even if DHS believes changes to the policy of AB 394 would be desirable from a public health and safety standpoint, neither DHS nor this Court has the authority to change the statutory mandate. Only the Legislature has that power. Respondent DHS' Emergency Regulation is inconsistent with its statutory mandate, and therefore must be set aside.[2]

[2] The Court does not hold that the initial minimum staffing ratios are "immutable," so long as DHS' discretion is properly exercised within the bounds of the statutory mandate.

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Respondent DHS argues that the decision to postpone implementation of the 1:5 minimum staffing ratio for medical/surgical units is consistent with the purposes of the statute because the Emergency Regulation only affects the timing of a "discretionary enrichment" of the staffing ratio, and does not affect the "minimum" staffing ratio (1:6) that was in place through all of 2004. This argument is without merit.

The notion that the 1:5 ratio was merely a "discretionary enrichment" is simply not supported by the evidence. As described in the Final Statement of Reasons for the Original Regulation, the change to 1:5 was not a discretionary "enrichment," but rather an incremental "phase-in" of the minimum ratio:

> "Commencing January 1, 2005, the nurse-to-patient ratio in medical, surgical, and combined medical/surgical units is proposed to change to 1:5 or fewer at all times. CDHS has decided to increase staffing on these unit shifts incrementally, by a later phase-in of this lower ratio." (CNA 44 [emphasis added]; see also CNA 891, 901 [same].)

DHS' use of the word "enrichment" to describe the proposed 1:5 ratio does not persuade that the ratio was not a minimum because throughout the rulemaking process DHS had referred to all of the minimum staffing ratios as "enrichments." For example, in setting the minimum staffing ratios for pediatric units -- which were not subject to an incremental phase-in -- DHS stated that "[t]his regulation will enrich staffing for the leanest one-quarter of pediatric hospital shifts in California." (CNA 37; *see also* CNA 12 [describing deferred changes to medical/surgical, step-down, specialty, and telemetry units as changes to "further" enrich staffing in those units," thereby inferring that both the initial ratios and the phased-in lower ratios were considered "enrichments"].) This shows that, to the extent the minimum staffing ratios increased the existing number of nurses on staff, DHS considered each of the minimum staffing ratios to be an "enrichment."

Further, this interpretation is the only one consistent with the statutory mandate of AB 394. Nothing in AB 394 gave DHS the discretion to "enrich" the ratios beyond the minimum necessary "to ensure the adequate protection of patients in acute care settings." Rather, as DHS properly determined, any "enrichment" to the minimum staffing ratios was intended to be implemented in accordance with the Patient Classification System (PCS). (CNA 956-57 [interpreting PCS as intended to remain in place "to enrich staffing above the minimum in response to patient acuity and patient care needs"]; *see also* Health & Safety Code § 1276.4(b) ["These ratios shall constitute the minimum number of registered and licensed nurses that shall be allocated. *Additional staff shall be assigned in accordance with a documented patient classification system* for determining nursing care requirements, including the severity of the illness, the need for specialized equipment and technology, the complexity of clinical judgment needed to design, implement, and evaluate the patient care plan and the ability for self-help care, and the licensure of the personnel required for care." (emphasis added)].)

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DHS effectively conceded that the 1:5 ratio was not a "discretionary enrichment" in its responses to public comments. In responding to a public comment questioning DHS' authority to implement "enrichments" in medical/surgical units, DHS responded:

> "According to the 2001 OSHPD figures, of the more than 70,000 acute care beds in California, more than 47,000 are designated as medical/surgical beds. (Designated perinatal beds are a distance second, with just over 6,400.) The mandate from HSC 1276.4 was to enrich staffing in order to improve the quality of patient care. Enriching staffing in those units which care for the majority of patients would have the most widespread and most immediate impact on the quality of care." (CNA 916 [emphasis added].)

Further, in response to specific comments about the phase-in of the proposed medical/surgical unit ratio, DHS stated:

> "CDHS has determined that the appropriate nurse-to-patient ratio for medical/surgical units shall be 1:5 or fewer at all times. CDHS is allowing a one-year period at 1:6 before the lower ratios is phased in. Please see rationale in the Statement of Reasons." (CNA 922, 1479 [emphasis added].)[3]

In the Statement of Reasons for the original Regulation, DHS indicated that it chose to phase-in the "richer ratios" for medical/surgical units for one year in order to allow providers time to develop a strategy for compliance (including budget planning), for the recruitment of additional nurses, and for the education and training of additional classes of nursing students. (CNA 21, 44-45.) DHS' decision to phase-in the original minimum staffing ratios was not challenged and, as a result, no court was called upon to decide whether the decision to increase staffing by an incremental phase-in of lower ratios was within the scope of the authority conferred on the DHS by the Legislature. However, in deciding to further postpone implementation of the lower ratios until January 1, 2008, DHS has placed this issue squarely before the Court.

AB 394 directed DHS to "establish minimum, specific, and numerical licensed nurse-to-patient ratios" which "shall constitute the minimum number of registered and licensed nurses that shall be [assigned]." (Health & Safety Code § 1276.4(a), (b).) It would be illogical to interpret AB 394 as requiring DHS to adopt minimum staffing ratios, while simultaneously giving DHS the unbridled discretion not to implement those ratios. The California Supreme Court reached a similar conclusion in *Clean Air Constituency v. California Air Resources Bd.* (1974) 11 Cal.3d 801. There, the Air Resources Board cited the energy crises of the early 1970's as an "extraordinary and compelling" reason to adopt a regulation delaying implementation of pollution control standards for automobiles. The Supreme Court issued a peremptory writ of mandate directing the Board to vacate its regulation and implement the legislation. The Court held

[3] In fact, decreasing patient/nursing ratios appears consistent with the finding by the Legislature that at the time of enactment, current staffing levels were unsafe and inappropriate.

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that the decision to delay implementation exceeded the scope of the Board's authority because energy conservation was not one of the goals of the legislation. (*Id.* at p. 814.)

Public health care policy specialists have debated, and likely will continue to debate, the wisdom of the Legislature's decision to require minimum safe staffing ratios. However, this is a matter outside the jurisdiction of this Court. All that is before the Court here is a statute and the question whether the Emergency Regulation exceeds the scope of lawful authority conferred on the DHS by such statute. The Court's interpretation is that it does.

B. Was the Emergency Regulation Reasonably Necessary to Effectuate the Purposes of the Statute?

Not only was the Emergency Regulation not within the scope of authority conferred by the statute, the Emergency Regulation also was not reasonably necessary to effectuate the purposes of the statute. Government Code section 11350 declares that, in addition to any other ground that may exist, a court may invalidate a regulation if it finds that the agency's determination that the regulation is reasonably necessary to effectuate the purposes of the statute is not supported by substantial evidence. (Govt. Code § 11350(b)(1); *Agri. Labor Relations Bd. v. Exeter Packers, Inc.* (1986) 184 Cal.App.3d 483, 492; *see also Ralphs Grocery Co. v. Reimel* (1968) 69 Cal.2d 172, 175.) The purpose of the Emergency Regulation at issue here was to prevent possible fiscal and other impacts on "a health care system already reported to be under stress" that might jeopardize the "availability of hospital services" in California. However, as described above, the purpose of the statute was to ensure the quality of care for patients in acute care settings. Thus, for the reasons set forth in this ruling, the Emergency Regulation was not reasonably necessary to effectuate the purposes of the statute.

Moreover, even if the purposes of the statute were deemed broad enough to include the risk of unintended consequences on the *availability* of hospital services in California, the Court still would find that there was not substantial evidence to support DHS' determination that postponing implementation of the 1:5 ratio was reasonably necessary to effectuate those purposes.

The "evidence" that DHS relied on fails to support its conclusion that staffing ratios are causing the "unintended consequences" of facility closures and shutdowns. The Finding of Emergency cites as justification for the Emergency Regulation "reports" of reductions in services at roughly a dozen hospitals, as reported in eight newspaper articles published between January and September, 2004. (CNA 2-3; *see also* CNA 392-419.) However, none of the articles reported that nurse-to-patient ratios were the primary cause for the closure or reduction of medical/surgical units at hospitals. The Pasadena Star News article reported the closure of Santa Teresita Hospital in Duarte, but made clear that the hospital's "financial woes" preceded the state-mandated increase in the ratio of nurses. (CNA 393 [reporting that "Santa Teresita's finances have been teetering on the brink of crisis" for the past three years].) The Los Angeles Business Journal discussed hospitals that had decided to close or downgrade their *psychiatric* units -- units that

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would not be affected by the Emergency Regulation. (CNA 396.) The New York Times and August 24 Los Angeles Times articles report closures of Los Angeles area emergency units, but attribute the primary cause of such closures to "charity care" (treating uninsured people) and state-ordered earthquake retrofitting, adding that the shortage of nurses is, at most, "adding to the distress." (*See* CNA 401-02, 405 ["Several factors have contributed to the problem, but the overwhelming one, according to hospital officials and healthcare economists, is the weight of the county's huge population of people without health insurance, who account for 1 in 3 emergency room visits"].) The Los Angeles Times article, in particular, quotes a healthcare economist as saying that "'[t]he nursing issue [is] driving higher healthcare costs, but is not a closure issue.'" (CNA 406.) The September 24 Los Angeles Times article reports that Robert F. Kennedy Medical Center would become the sixth Los Angeles County emergency room to close its doors in 2004 because of financial problems. The article states the hospital was hit by rising costs for nurses to meet the ratios and by the heavy expense of seismic retrofitting. However, the article acknowledges that the hospital had been losing money for years -- it lost $52 million since January 2002 -- primarily because the hospital was not generating enough business for inpatient services that insurance typically covers. (CNA 408.) The San Jose Mercury News article reports that some hospitals in Santa Clara County say they are turning ambulances away from emergency rooms because of inadequate staffing, but the article also states that the new mandate means those being treated at emergency rooms are receiving higher quality care, and concludes that it is "too early to tell" if the new ratios are "too much of a strain on hospitals trying to meet the mandate." (CNA 410.) The Press Enterprise article describes layoffs of 26 people at Hemet Valley Medical Center and states that the ratios and "[t]he doubling of workers' compensation premiums" were cited as "two of the reasons" for the layoffs, but the article shows that the health facility had been losing money since 1998 ($2.7 million in the red in FY 2003), and had laid off 70 employees the year before the ratios took effect. (CNA 411-12.) The USA Today article discusses the alleged nursing shortage and indicates that complying with the ratios "won't be cheap," but the article does not attribute any closures or reductions in services to the ratios. (CNA 413-16.)

In addition to the newspaper articles, DHS' Finding of Emergency mentions an April 30, 2004, e-mail from the Chief Executive Officer at San Gabriel Valley Medical Center, and a May 7, 2004, letter from the Chief Operating Officer at Western Medical Center. Both communications relate to interruptions in service at *psychiatric/mental health* units. (CNA 399-400.) Since the Emergency Regulation would not in any way alter the staffing ratios for those units, neither communication supports the agency's Findings in support of the Emergency Regulation.

In sum, the only "evidence" considered by DHS discussed closures at psychiatric units and emergency departments -- not medical/surgical units -- and the "evidence" attributes such closures primarily to long-standing financial burdens on health care providers associated with the growing number of uninsured patients and, to a lesser extent, the costs of mandatory earthquake retrofitting requirements.[4] None of the

[4] DHS argues that it also discovered that its on-site study had actually underestimated the number of nurses needed to meet the minimum of 1:6 by failing to account for the "at all times" requirement. (DHS

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"evidence" establishes any basis to postpone the minimum 1:5 ratio for medical/surgical units.

CHA and DHS now argue that because the initial minimum staffing ratios in medical/surgical units were not supported by "independent empirical" data, the initial ratios were nothing more than a "guess" about what the appropriate staffing ratios should be. They argue that DHS must therefore have the discretion to revise such ratios. The Court does not agree. First, the "lack of independent empirical" support for the initial staffing ratios does not justify annulling such ratios by emergency fiat. Second, although there may not have been "independent empirical" information to support the medical/surgical ratio, this does not mean that the ratio was selected out of thin air. Rather, the record shows that the ratios were based on voluminous sources of information, including the work of many professional organizations and literally thousands of public comments. (CNA 892, 913-14, 916.) DHS itself argued in support of such ratio in *CHA v. DHS* (Case No. 03CS0184): "There is substantial evidence in the rulemaking file to support the reasonable necessity of [the] minimum ratios . . . ." (CNA 1640-41.) Third, the alleged lack of evidence to support the initial minimum ratio does not, by itself, serve as evidence to support a different ratio. The Court cannot ignore that at the time it adopted the Emergency Regulation, DHS still did not have any "independent empirical" information about appropriate staffing levels in medical/surgical units; there was no new evidence to support the change in the ratio.

DHS' determination that the Emergency Regulation is reasonably necessary to effectuate the purposes of the statute is not supported by substantial evidence.

C. Did DHS Abuse its Discretion in Proceeding by Emergency Regulation?

Even if the Court were not inclined to interpret the statute to prohibit considerations of economic interest, the Court still would find in favor of CNA on its claim that the Emergency Regulation was an abuse of discretion and not adopted in the manner required by law.

An emergency regulation requires a finding that it "is necessary for the immediate preservation of the public peace, health and safety or general welfare."[5] (Govt. Code § 11346.1(b).) Because what constitutes an emergency is primarily a matter for the agency's discretion, courts generally must give deference to an agency's finding of

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Opposition, p. 8.) There are several problems with this argument, the most important being that there is no indication DHS relied on this purported error as a basis for the Emergency Regulation. In addition, the record shows that DHS did not rely (at least not exclusively) on the on-site study to set the ratios. (*See, e.g.*, CNA 916.) Among other things, it also relied on the OSHPD data which, it noted, was likely to overestimate the actual amount of care required. (CNA 470.) Moreover, the "at all times" issue was nothing new; it arose before the ratios were adopted. In its Initial Statement of Reasons, DHS indicated that the ratios were intended to represent the maximum number of patients "assigned to any one nurse during any shift." (CNA 477.)

[5] Any finding of emergency must include a written statement which contains the information required by paragraphs (2) to (6), inclusive, of subdivision (a) of Section 11346.5 and a description of the specific facts showing the need for immediate action. (Gov. Code § 11346.1(b).)

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emergency. (*Schenley Affiliated Brands Corp. v. Kirby* (1971) 21 Cal.App.3d 177, 194-95.) However, a court is not absolutely bound by an agency's finding of emergency and a court may overturn such a determination when there has been an abuse of discretion. (*Doe v. Wilson* (1997) 57 Cal.App.4th 296, 305-06.) Specifically, a court may overturn such a determination when the court finds the action is arbitrary, capricious, or entirely lacking in evidentiary support, or that the agency has failed to follow the procedures established by law. (*Schenley Affiliated Brands, supra*, at pp. 196-97; *Pitts v. Perluss* (1962) 58 Cal.2d 824, 833.) Moreover Government Code section 11350 expressly provides that an emergency regulation may be declared invalid upon the ground that the facts recited in the statement of emergency do not, in fact, constitute an "emergency." (Govt. Code § 11350(a).)

The definition of "emergency" has long been accepted in California as an unforeseen situation calling for immediate action. (*Doe v. Wilson*, *supra*, at p. 306.) Here, DHS claims that its finding of emergency was not an abuse of discretion because it received "reports" that the nurse-to-patient ratio regulation was compromising patient access to services, quality of care, and the accessibility and availability of nurses to care for patients, which created an "unexpected emergency." (DHS Opening Brief, p. 18.)

However, DHS concedes, as it must, that it knew *before* enacting the original regulation of the claims that the nursing shortage in California was severe and that there was a possibility of hospital closures and other reductions in services. Based on a review of the history of AB 394 and DHS Regulation R-37-01, there can be no doubt that both the Legislature and DHS were aware that the staffing ratios were going to have a significant financial impact on the hospital industry. For example, the April 6, 1999, report of the Assembly Committee on Health detailed the hospital industry's opposition to legislatively mandated nurse-to-patient ratios for acute care hospitals:

> "CHA states that passage of this bill will put hospitals in the position of being non-compliance because they will not be able to hire the nurses required. . . . [¶] CHA states that the ratios in this bill have no analytical basis, that staffing ratios will lead to inefficiency, and that this bill could cost hundreds of millions for hospitals with no reimbursement. Absent additional revenue, CHA states that the overall level of patient care could suffer because hospitals may decide to limit the number of patients they admit in order to accommodate the ratio requirements. If hospitals are able to find nurses to hire and lay off aides and other personnel to pay for the additional nurses, then there will be service gaps." (*See* CNA 976-83 (emphasis added).)

Similarly, an Assembly Republican Bill Analysis for AB 394 stated that the CHA "has estimated the statewide costs of this bill to be hundreds of millions of dollars." (CNA 1049.)

In a letter to the Governor requesting that he veto AB 394, CHA wrote the following:

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> "Ratios could have unintended consequences for patients. For example, hospital[s] may need to limit admissions in order to meet ratios, depending on the specific ratios adopted. Absent new revenue, laboratory, pharmacy, and other hospital services may have to be cut back to fund more nursing positions. These changes also will have adverse consequences." (CNA 1055 [emphasis added].)

In addition, the Initial Statement of Reasons for the original DHS regulation provides:

> "[Representatives of CHA] stated that if hospitals cannot comply with the mandated ratios, hospitals will be forced to close units and suspend services, thus limiting, and possibly denying, access to care for many Californians. Closures and suspensions in services could, in turn, cause lengthy patient transports, delays in start of care, and potentially, increased morbidity and mortality." (CNA 468.)

> "CHA's caution about imposing ratios that will place heavy and unnecessary burdens on the financial reserves of providers deserved and received thoughtful and deliberate consideration." (*Id.*)

The Statement of Determinations for the original Regulation indicates that the DHS "has made an initial determination that the amendment of these regulations may have a significant statewide adverse economic impact on business," (CNA 491, 582), and that DHS anticipated "some hospitals may curtail services by closing units if they are not able to comply with the proposed regulations." (CNA 492.) DHS' estimated the statewide economic impact of the regulations at $164,985,000 in FY 2003-04, $408,230,000 in FY 2004-05, and $486,490,000 annually thereafter for non-state-operated hospitals. (CNA 493, 581.)

It is noteworthy that notwithstanding concerns that hospitals might decide to limit the number of patients they admit in order to accommodate the ratio requirements, prior to implementing the original Regulation, DHS rejected numerous requests that the 1:5 ratio for medical/surgical units be delayed beyond January 1, 2005, due to the "enormous burden" put on hospitals by the nursing shortage. (*See, e.g.*, CNA 889.) DHS consistently declined to delay implementation of the proposed 1:5 ratio because the "regulations have already been delayed from their mandated implementation date of 01/01/02" and because it concluded that "the nursing shortage is outside the scope of this rulemaking package." (CNA 889, 891, 895, 909, 1475-77, 1495-97, 1502-05.)

To summarize, the evidence shows that before adopting the original staffing regulation, the consequences of nurse-to-patient ratios, including the "heavy burden" it would place on hospitals' financial reserves, were fully anticipated to threaten access to health care "for many Californians." (CNA 11-21.) Assuming these threats are even

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relevant to a proper determination of the minimum staffing ratios, the evidence shows that these risks were well known before DHS adopted the initial staffing regulation. Therefore, additional "reports" of these same risks can hardly create "an unforeseen situation" calling for immediate action.

In support of its Finding of Emergency, DHS claims that even though it knew about these risks, it was incapable of anticipating whether the risks actually would come to pass, or the magnitude and scope of the impact that they would have. DHS contends that when it received the "reports" that hospitals were reducing services, and when it learned the magnitude and scope of these impacts to the health care system, DHS determined that the Emergency Regulation was necessary for the immediate preservation of public health and safety.

However, this argument is not supported by the evidence. DHS did not offer any new data, studies or other evidence to support its claim that it learned the magnitude and scope of these threats to patient care were any more severe than originally anticipated. The "evidence" that DHS relies on for its decision to proceed by emergency regulation consists almost entirely of second-hand "reports" of hospitals closing or reducing the availability of certain kinds of services, and nothing shows that the magnitude and scope of the reductions in service were more severe than originally anticipated.

To attempt to compensate for the lack of evidence to support DHS' finding of emergency, DHS submits the declaration of Jamie Daigle, which attaches a "new study" and numerous other documents generated by, or submitted to, DHS as part of the post-November 4, 2004, rulemaking file for the Emergency Regulation (i.e., after the adoption of the Emergency Regulation). Similarly, DHS relies on the Declarations of Barbara Gallaway and Gina Henning as containing "evidence" that supports DHS' actions, without any showing that DHS in any way relied on such evidence at the time it adopted the Emergency Regulation. DHS cites to these declarations as though they are evidence that should be considered by the Court to support the Emergency Regulation. This is not correct.

The law is settled that in reviewing quasi-legislative acts of administrative agencies, judicial review is limited to an examination of the proceedings before the agency. (*California Assn. of Nursing Homes v. Williams* (1970) 4 Cal.App.3d 800, 811, 815-16; *see also* Govt. Code § 11350(a); *California Medical Association v. Brian* (1973) 30 Cal.App.3d 637, 652.) Moreover, Government Code section 11346.1(b) specifically requires that "a description of the specific facts showing the need for immediate action" must be contained in the actual finding of emergency. Accordingly, the Court only considers the "evidence" relied on by DHS in adopting the Emergency Regulation and properly before the Court. Based on such evidence, the Court has concluded that there is no basis for DHS' finding of emergency.

Moreover, even if there was evidence showing that the magnitude and scope of hospital closures was more severe than originally anticipated, there is no evidence showing that the proximate cause of such closures was the DHS staffing regulation.

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Importantly, the record before the Court shows that hospitals were closing and citing economics and staff shortages as their bases well before the original regulation took effect on January 1, 2004. (*See* February 17, 2005, Declaration of Gina Henning, Exh. C; *see also* CNA 334-36, 635, 637-38, 645-648, 652-659, 660-674, 718-719, 721-724, 726-736.) DHS undertook no effort to distinguish the new "reports" of hospital closures from the earlier reports of hospital closures made prior to enactment of the regulation. As a result, DHS has failed to establish any nexus between the reported closings and the implementation of the staffing regulations.

Finally, it is important that DHS does not even contend the "reports" of hospital closures are true. To the contrary, DHS admits that "it does not have data to support or refute these and other claims that have been made about problems caused or exacerbated by the current nurse-to-patient ratios." (CNA 3.) DHS simply concludes that "it is inappropriate to risk unintended consequences of enriched nurse-to-patient ratios on the availability of hospital services in California." (*Id.*) This appears disingenuous given the record before the Court.

The Court finds that it was an abuse of discretion for DHS to determine that deferring the 1:5 ratio for Medical/Surgical Units was necessary for the immediate preservation of public health and safety.

A final point raised by CHA is that even if there was no new evidence of the risk of hospital closures, DHS nevertheless must have the ability to "change its mind" and reach a different conclusion based on the same evidence. This argument is problematic from a credibility standpoint, given the voluminous record in support of the original determination. Further, this does not resolve the problem that their new position is inconsistent with the purposes of the statute. And most important here, DHS still failed to explain how the alleged new evidence, which it claims to have received as early as the very first month after the initial regulations took effect, could be ignored for 11 months, and then suddenly used to justify an "emergency" regulation.

The other changes effected by the Emergency Regulations -- namely, (i) the clarification of when nurses shall be counted towards the ratios; (ii) the change in the recordkeeping requirements for emergency departments; and (iii) the decision to allow emergency departments temporarily to deviate from the ratios in the event of "saturation" -- also were an abuse of discretion. The Finding of Emergency for R-01-04E states that it is "critical" to clarify the definition of "at all times," but there is no discussion of why such clarification is critical. For example, there is no discussion of the magnitude of the problem caused by the alleged uncertainty surrounding the previous definition or the reason the change cannot be implemented in accordance with the normal rulemaking procedures. (CNA 2-6, 337-44.) To the contrary, the Initial Statement of Reasons for the Emergency Regulation indicates that, as a result of a different lawsuit, the "at all times" requirement was found to be valid and "sufficiently clear" and that DHS is enacting the Emergency Regulation merely to make the meaning of the requirements "even more explicit." (CNA 338.) In addition, at the hearing, DHS effectively conceded that the "at

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all times" clarification was not an emergency by indicating that it was included in the Emergency Regulation for administrative purposes.

Similarly, the Finding of Emergency states that it is necessary to adjust the terminology and method of recording nurse assignments to patients for hospital emergency departments, but the only reason offered for the change is that the amendments would make the application of the ratios "more congruent" with reality and allow hospitals needed flexibility in staffing. (CNA 3-4.) Again, there is no discussion of the magnitude of the problem or the reason the change cannot be implemented pursuant to the normal rulemaking procedures. (CNA 2-6, 337-44.)

Under Government Code section 11350(a), a regulation may be declared invalid if a court finds that the facts recited in the statement of emergency do not in fact constitute an emergency. Here, the Court finds that the facts recited in the Finding of Emergency do not constitute an emergency. Accordingly, the Court finds the determination of "emergency" is arbitrary and capricious and entirely lacking in evidentiary support.

For these reasons, the Court concludes that DHS abused its discretion and failed to follow the procedures required by law in determining that the Emergency Regulations were necessary for the immediate preservation of public health and safety.

D. DHS' Readoption of the Emergency Regulation

Because the second Emergency Regulation adopted on March 3, 2005, is identical in format and content to the first Emergency Regulation, the Court treats both Emergency Regulations the same, i.e., both Emergency Regulations must be set aside for the reasons stated above. The Court finds it unnecessary to decide whether re-adoption of the same Emergency Regulation violated the Court's injunction ruling and/or APA section 11346.1(e).

E. Conclusion

The Court finds that the Emergency Regulations must be set aside because (i) the regulations are not within the scope of the authority conferred by the statute; (ii) there is not substantial evidence to support the determination that the regulations are reasonably necessary to effectuate the purposes of the statute; and (iii) DHS abused its discretion and failed to follow the procedures established by law in determining that the regulations were necessary for the immediate preservation of public health and safety.

Accordingly, the Court grants CNA's request for a peremptory writ of mandate commanding respondents to set aside each of the Emergency Regulations; for a declaration that the Emergency Regulations do not comply with Government Code sections 11342.1, 11342.2, and 11346.1, and are unlawful; and for a permanent injunction enjoining the implementation and enforcement of the Emergency Regulations. The Court declines to enjoin ongoing DHS rulemaking proceedings, if any, to adopt permanent non-emergency regulations. A peremptory writ of mandate shall issue directing Respondents

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Sandra Shewry and DHS to set aside the Emergency Regulations. Respondents shall file a return to the peremptory writ of mandate within 30 days after it is served on them describing what steps they have taken to comply with the writ.

CNA is directed to prepare a formal order, attaching the Court's ruling as an exhibit, and a judgment and writ of mandate consistent with the ruling; submit them to opposing counsel for approval as to form; and thereafter submit them to the Court for signature and entry of judgment in accordance with Rule of Court 391. The preliminary injunction shall remain in effect pending issuance of the permanent injunction.

Any request for fees or costs shall comply with the Code of Civil Procedure and all state and local rules.

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